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Hsiao-Wecksler et al.

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(45) **Date of Patent: Nov. 1, 2016**

(54) **PORTABLE ACTIVE PNEUMATICALLY POWERED ANKLE-FOOT ORTHOSIS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1174 days.

(21) Appl. No.: **13/419,958**

(22) Filed: **Mar. 14, 2012**

(65) **Prior Publication Data**

US 2012/0289870 A1 Nov. 15, 2012

Related U.S. Application Data

(63) Continuation-in-part of application No. 12/898,519, filed on Oct. 5, 2010, now abandoned.

(60) Provisional application No. 61/452,523, filed on Mar. 14, 2011.

(51) **Int. Cl.**
A61H 1/02 (2006.01)
A61H 3/00 (2006.01)

(52) **U.S. Cl.**
CPC ***A61H 1/0266*** (2013.01); ***A61H 3/00*** (2013.01); *A61H 2201/165* (2013.01); *A61H 2201/5041* (2013.01); *A61H 2201/5061* (2013.01); *A61H 2201/5069* (2013.01); *A61H 2201/5071* (2013.01)

(58) **Field of Classification Search**
CPC A61H 1/0266; A61H 3/00; A61H 2201/165; A61H 1/0237; A61H 1/0262; A61F 2/66; A61F 2002/74; A61F 2002/747; A61F 2002/748
See application file for complete search history.

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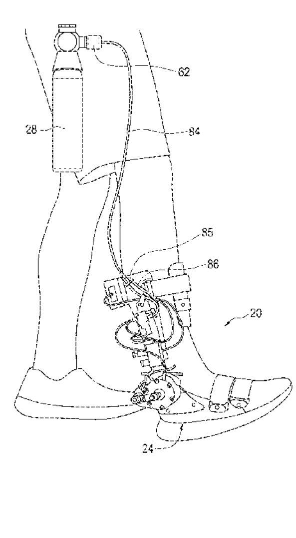
(57) **ABSTRACT**

A portable active fluid-powered ankle foot orthosis. A lower leg mount and a foot bed are pivotally coupled at or proximate to an ankle position. A fluid powered rotary actuator is configured to receive power from a wearable fluid power source and provide controlled force and resistance to aid or inhibit relative rotation of the foot bed and the lower leg mount. An integral controller is provided for receiving data from sensors and controlling the fluid powered rotary actuator to actively assist gait of a user.

17 Claims, 23 Drawing Sheets



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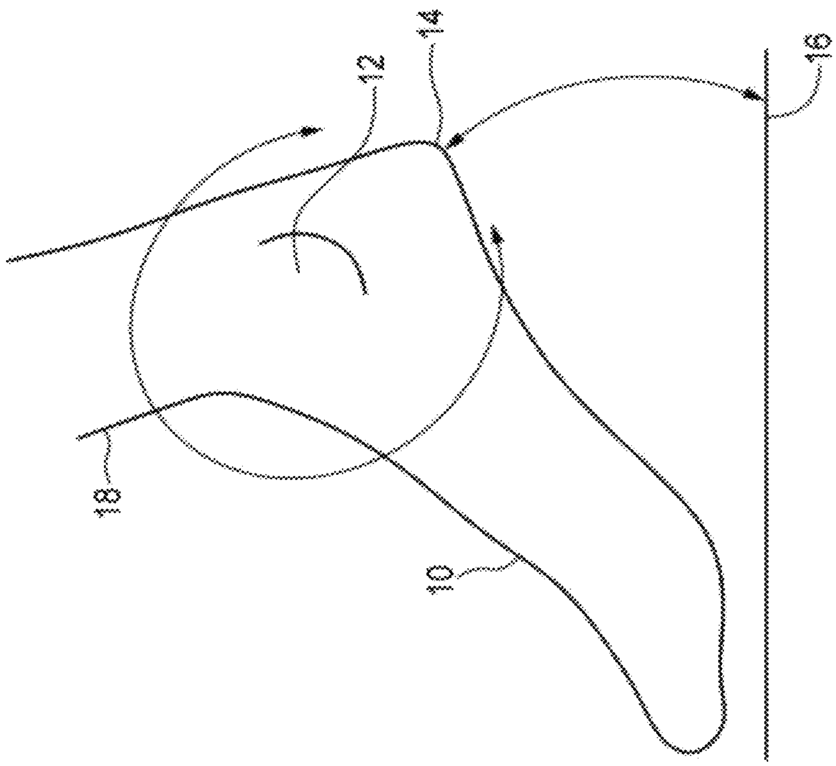

FIG. 1

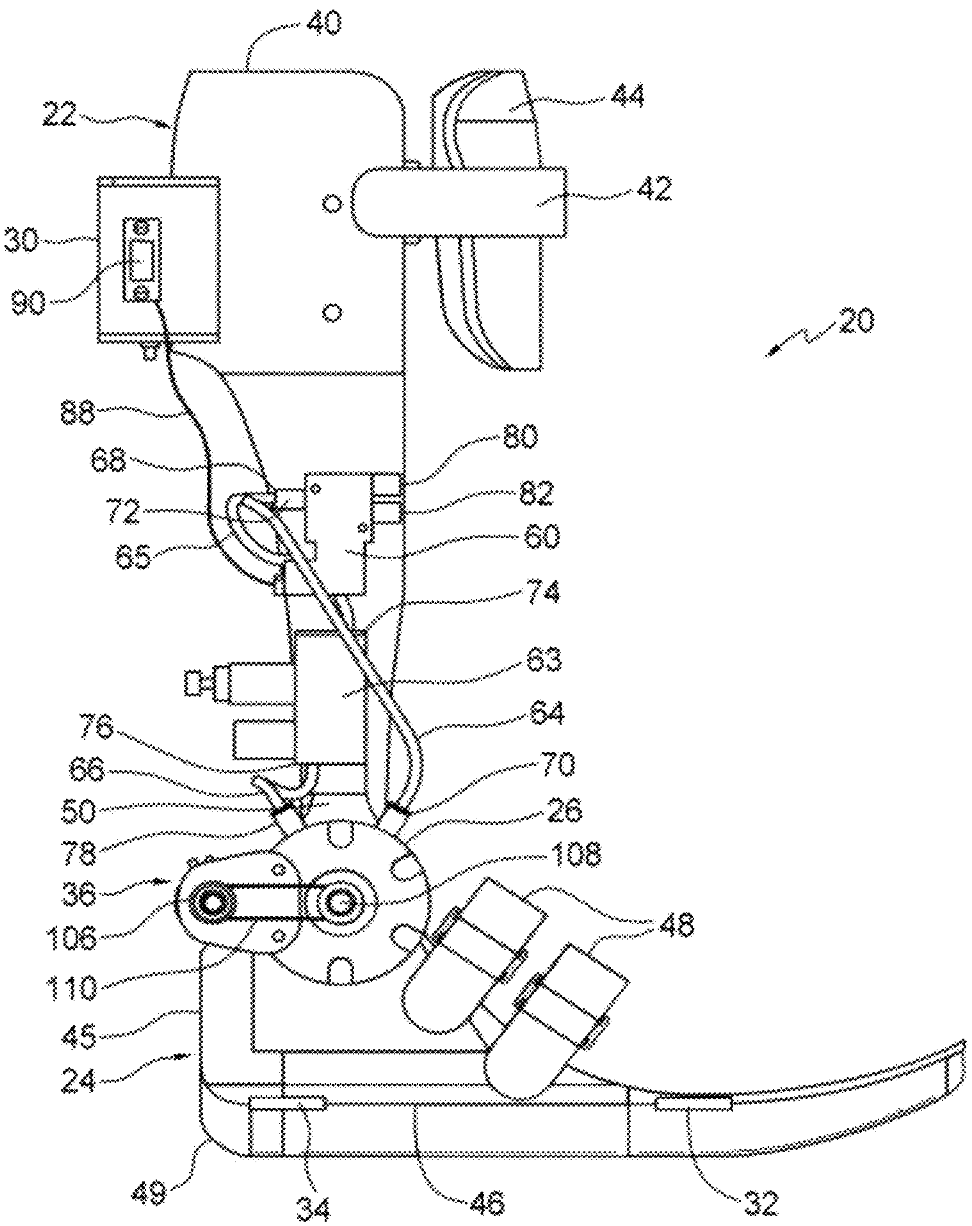
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FIG. 2

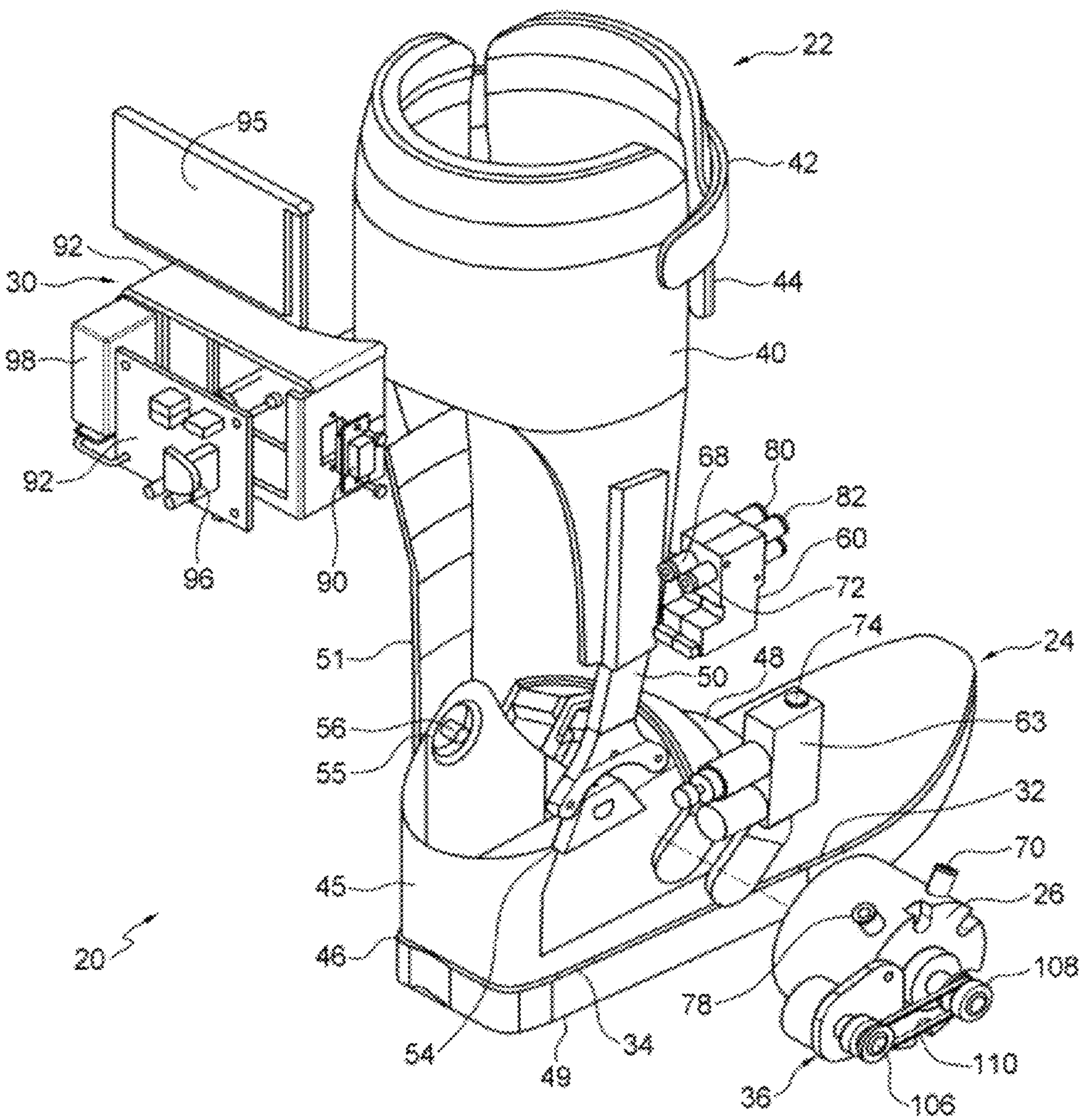
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FIG. 3

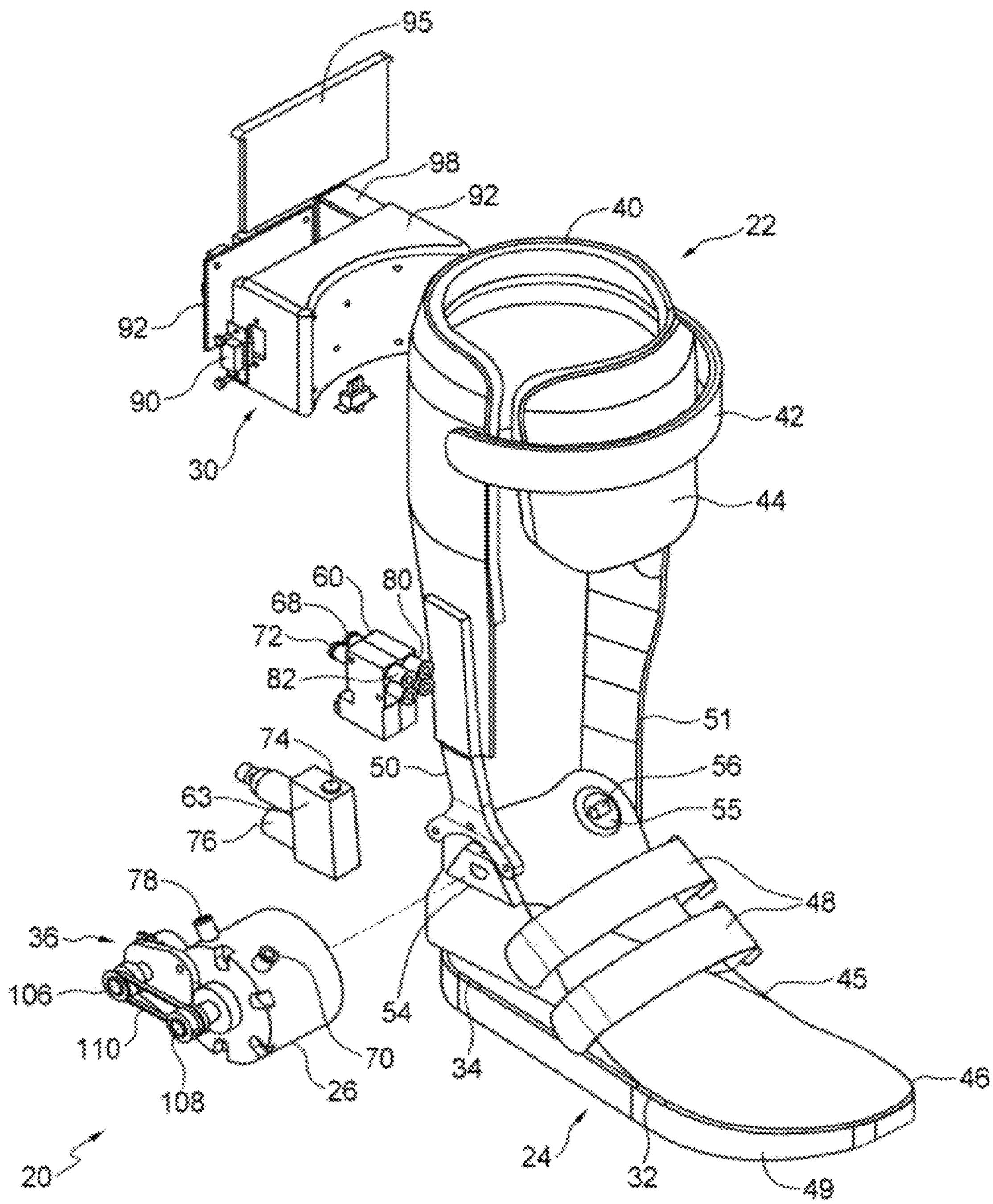
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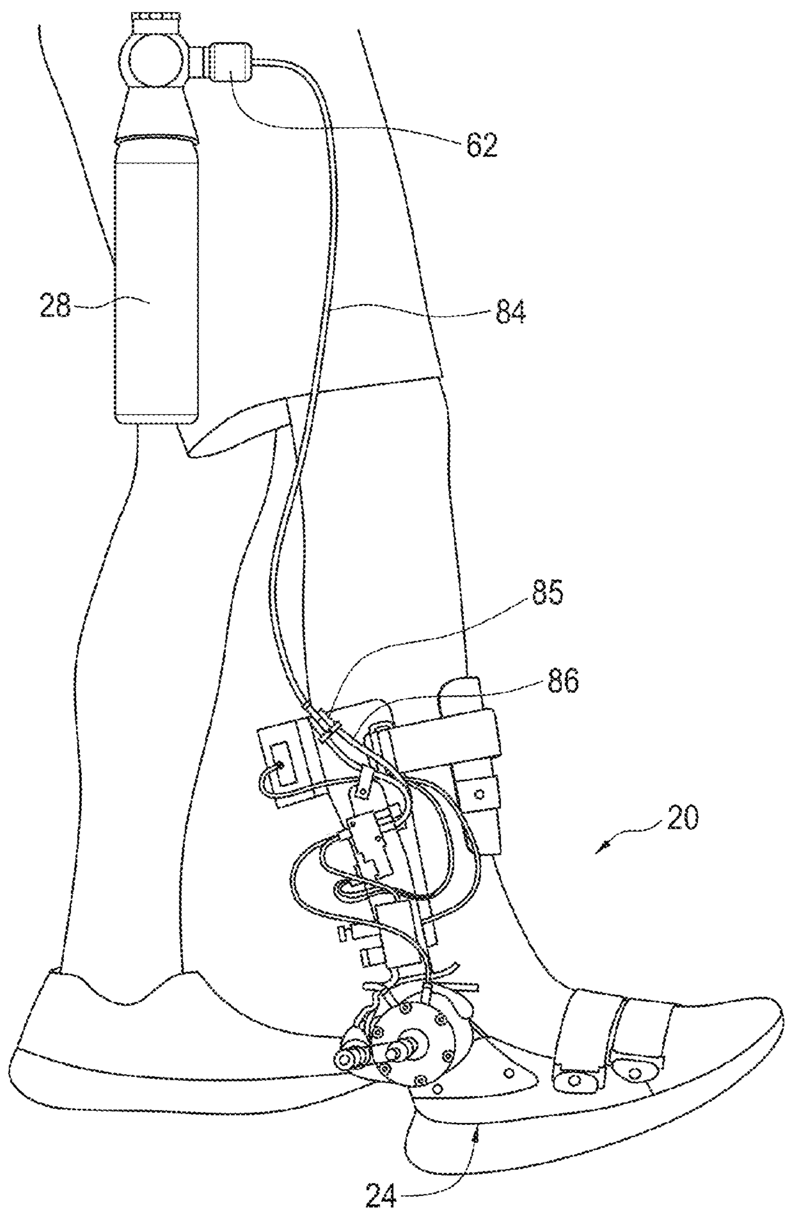
FIG. 4



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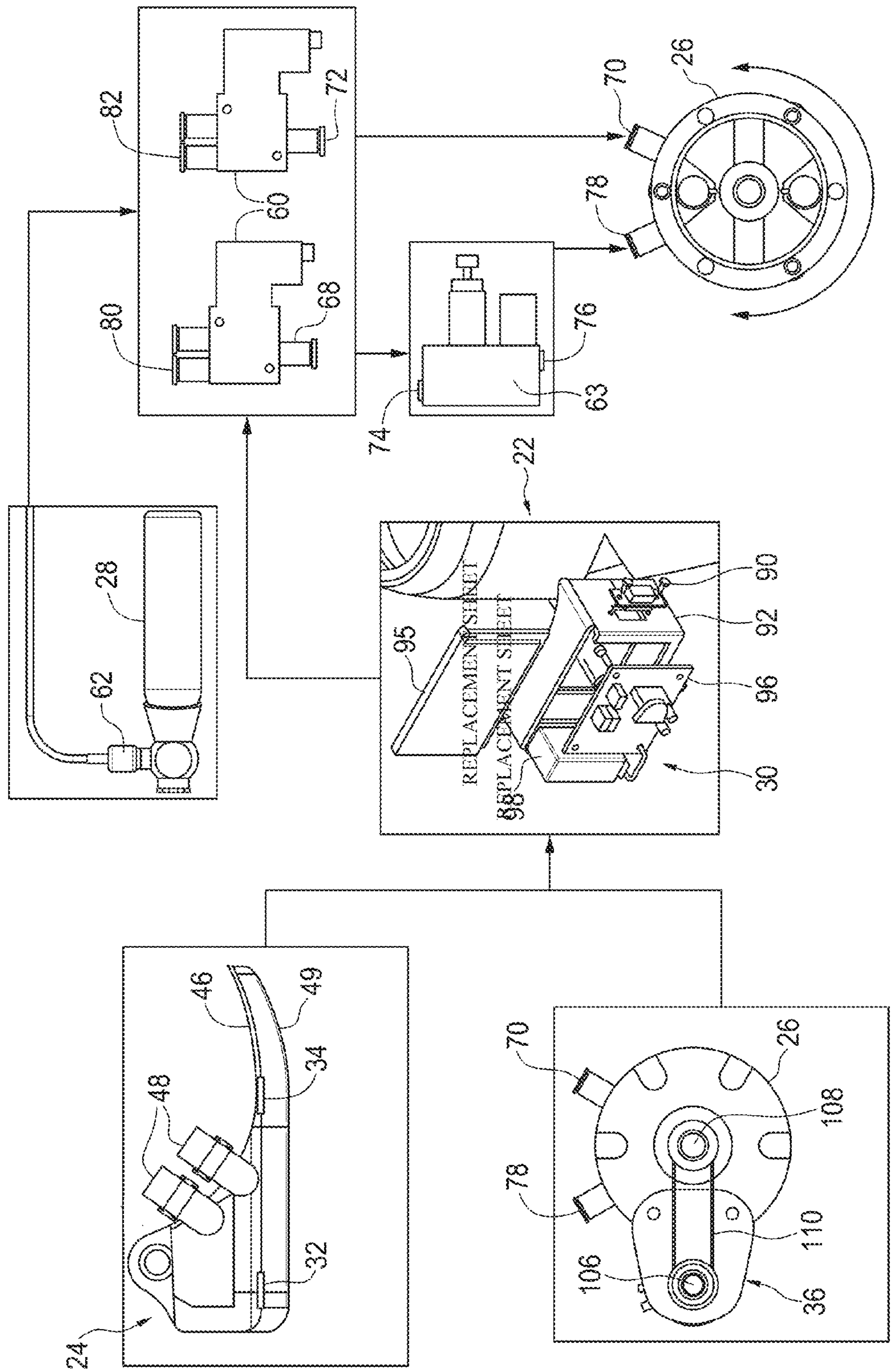
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REPLACEMENT SHEET
REPLACEMENT SHEET
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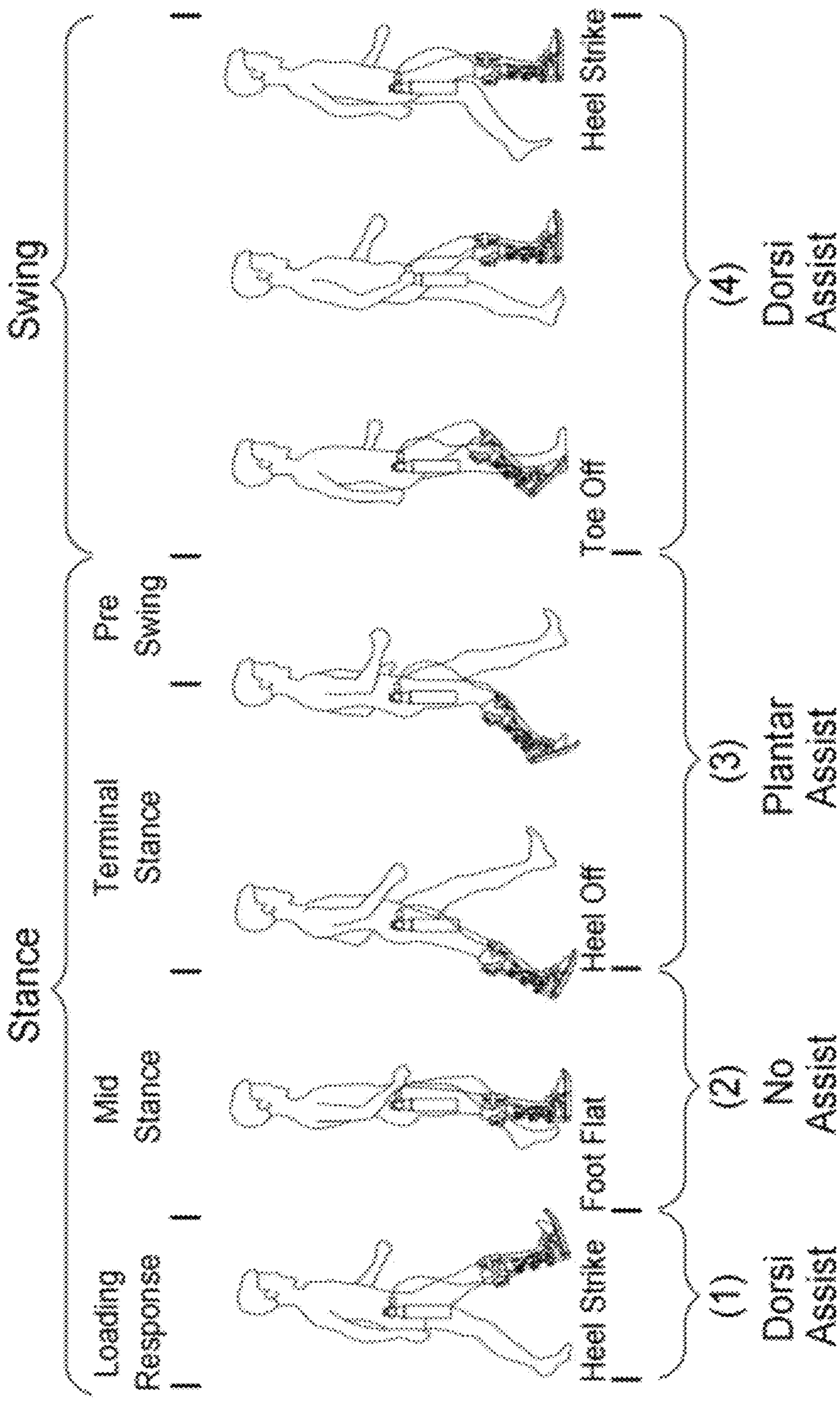
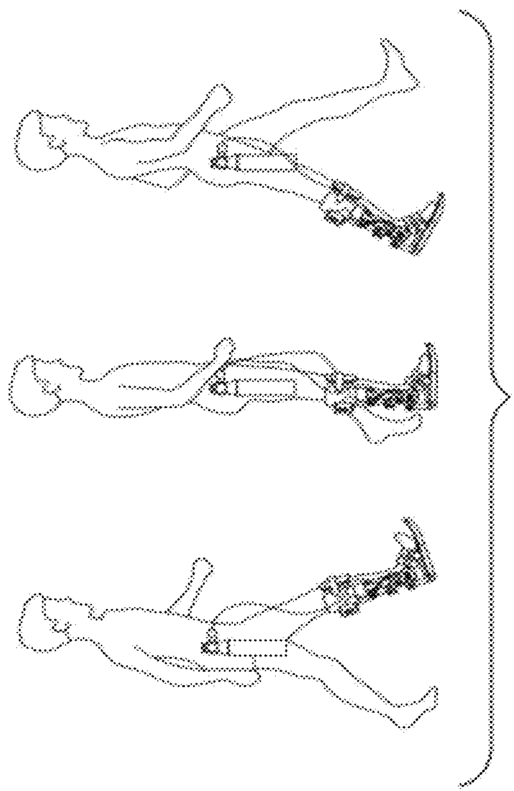
FIG. 6



Stance
Swing
Loading Response
Mid Stance
Terminal Stance
Pre Swing
Heel Strike
Foot Flat
Heel Off
Toe Off
Heel Strike
(1) Dorsi Assist
(2) No Assist
(3) Plantar Assist
(4) Dorsi Assist

FIG. 7



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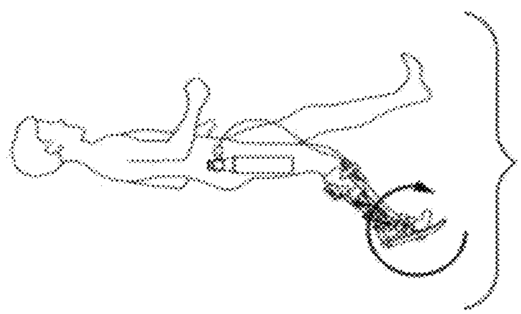


FIG. 9

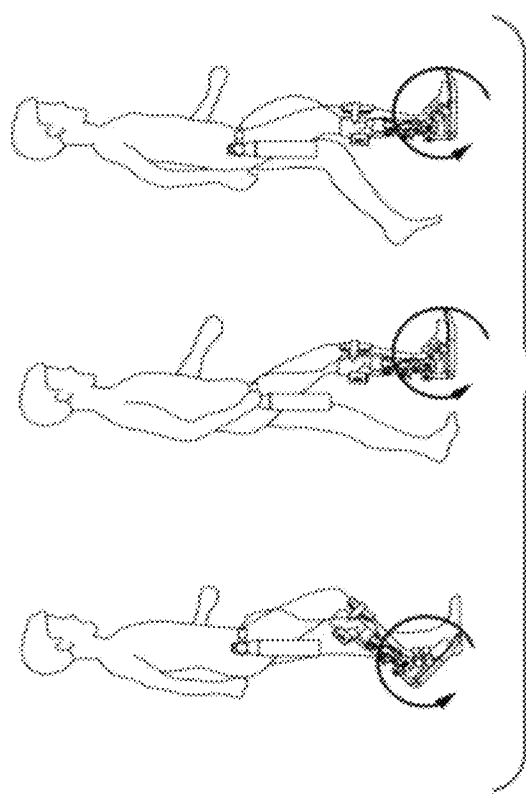
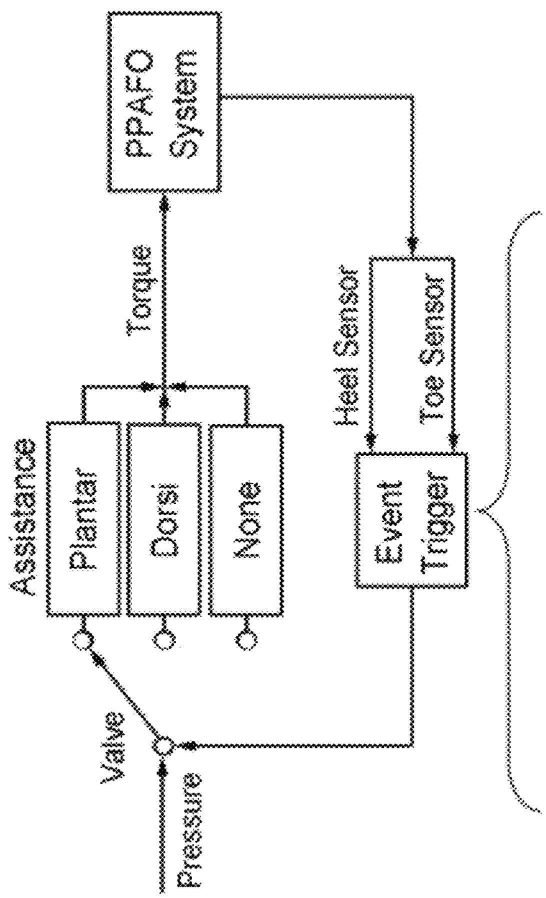


FIG. 10



Gait Event	Heel Sensor on	Heel Sensor off	Toe Sensor on	Toe Sensor off	Torque Assist
Heel Strike	x			x	Dorsi
Foot Flat	x		x		None
Heel Off		x	x		Plantar
Toe Off		x		x	Dorsi

FIG. 11

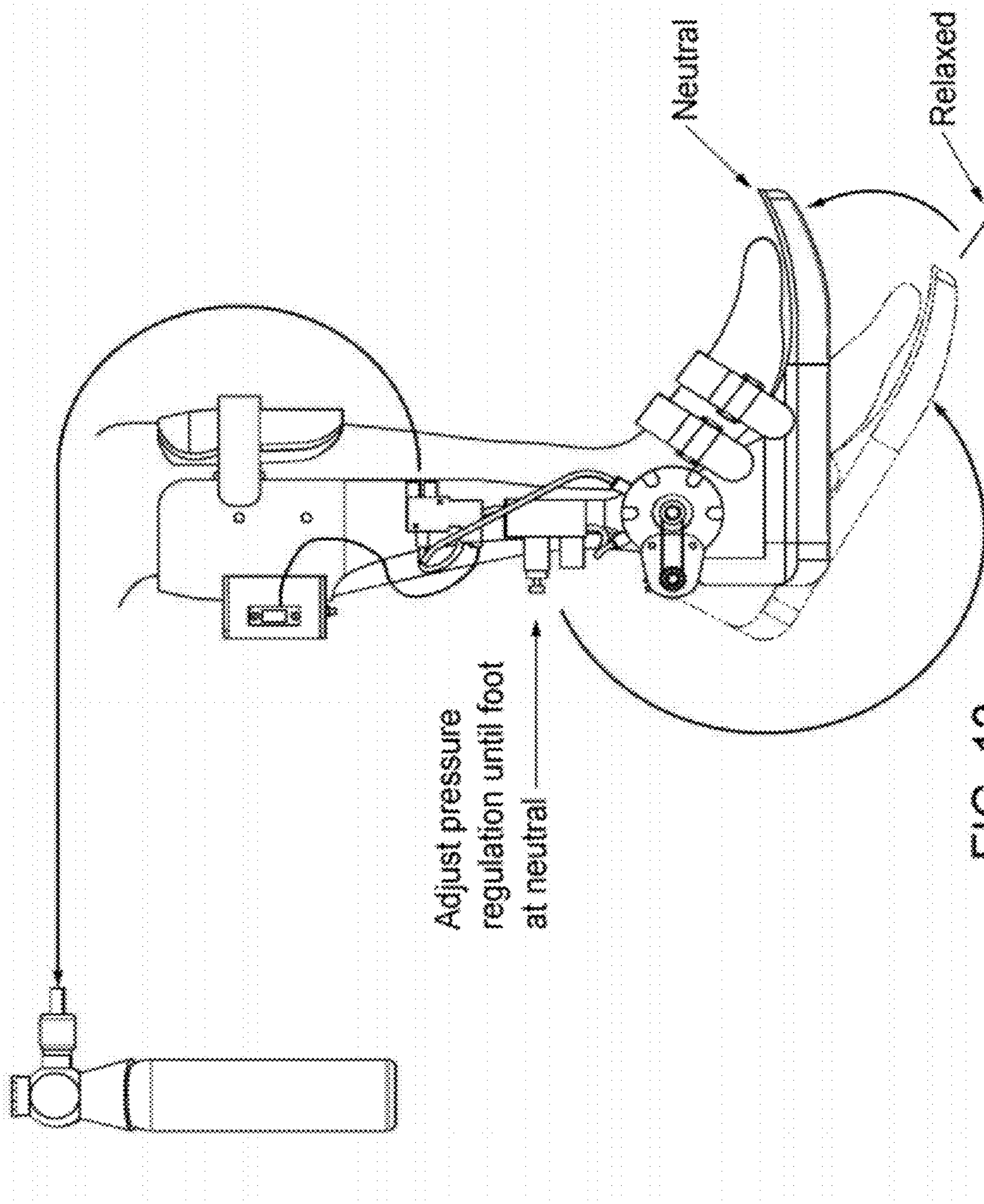

Neutral
Relaxed
Adjust pressure regulation until foot at neutral

FIG. 12

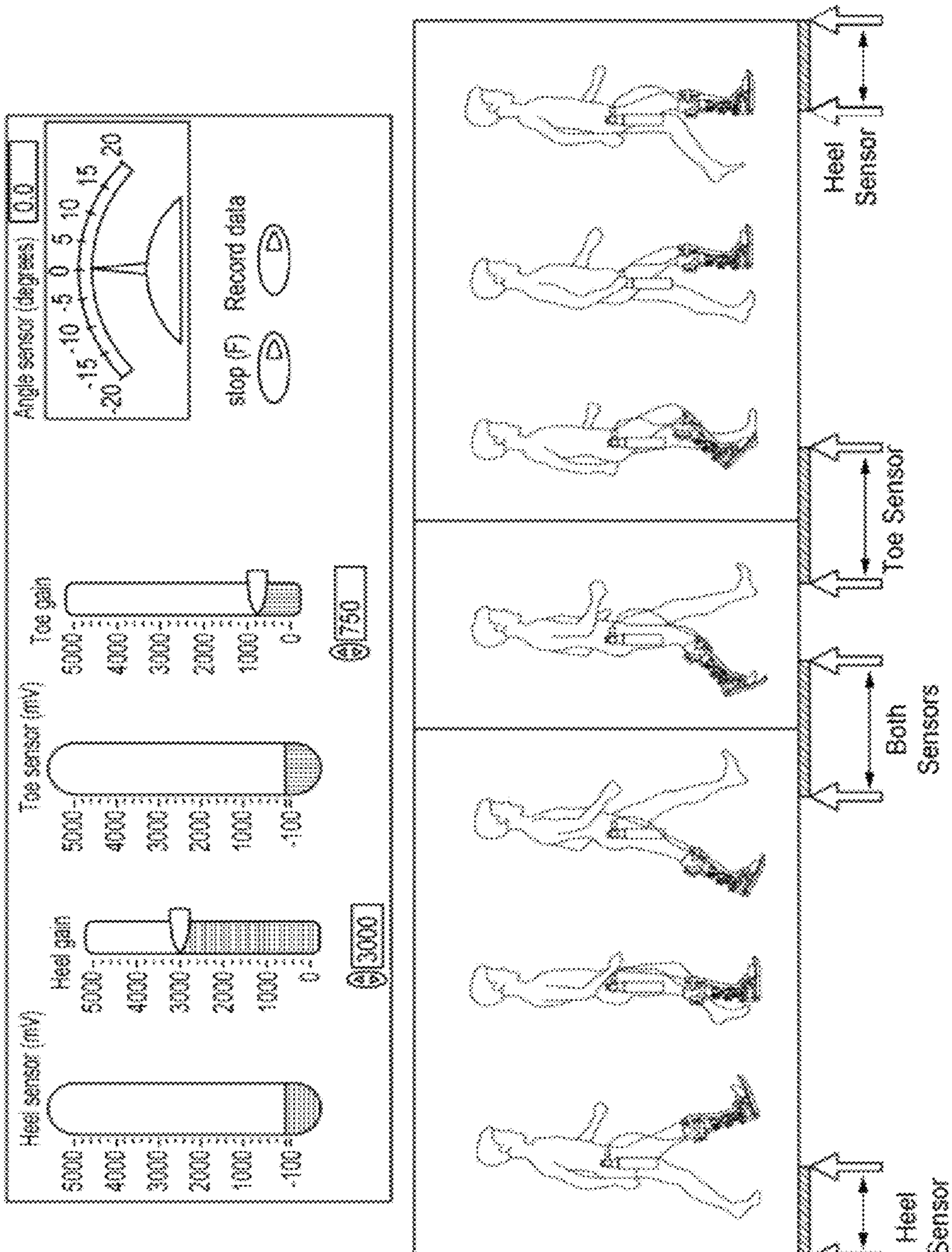
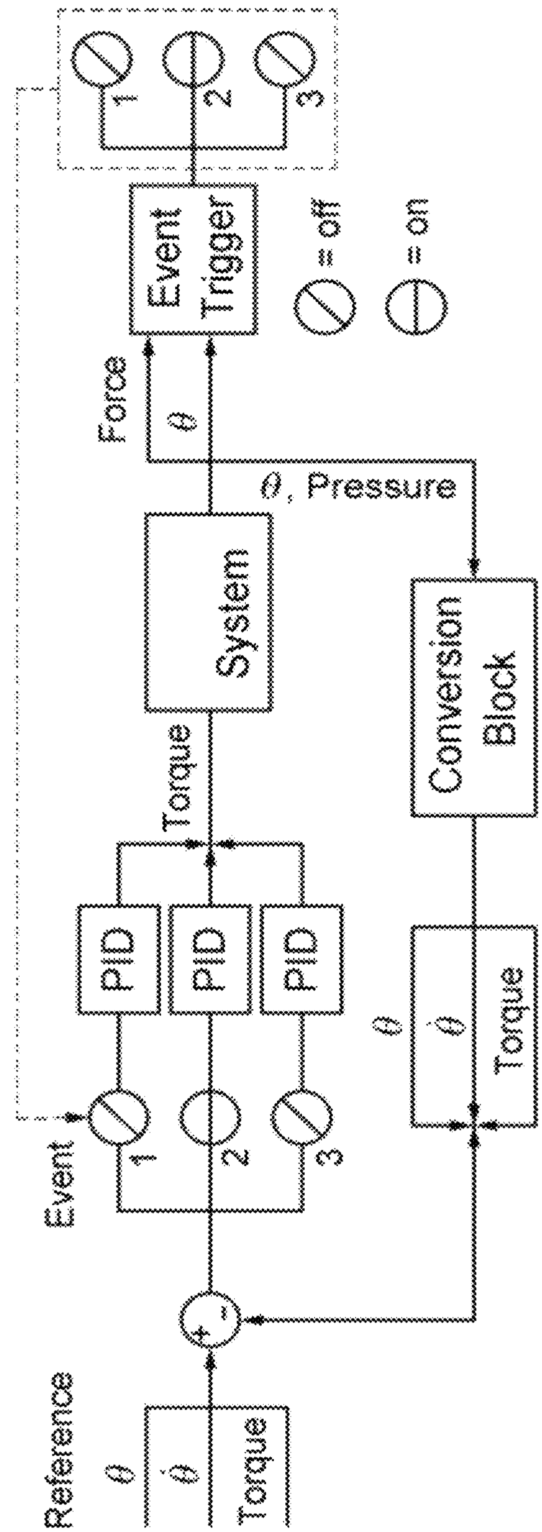

Heel sensor (mV)
Heel gain
3000
Toe sensor (mV)
Toe gain
750
Angle sensor (degrees)
0.0
stop (F)
Record data
Heel Sensor
Both Sensors
Toe Sensor
Heel Sensor

FIG. 13



Reference
θ
$\dot{\theta}$
Torque
Event
1
2
3
PID
PID
PID
Torque
System
θ, Pressure
Force
θ
Event Trigger
1
2
3
= off
= on
Conversion Block
θ
$\dot{\theta}$
Torque

FIG. 14

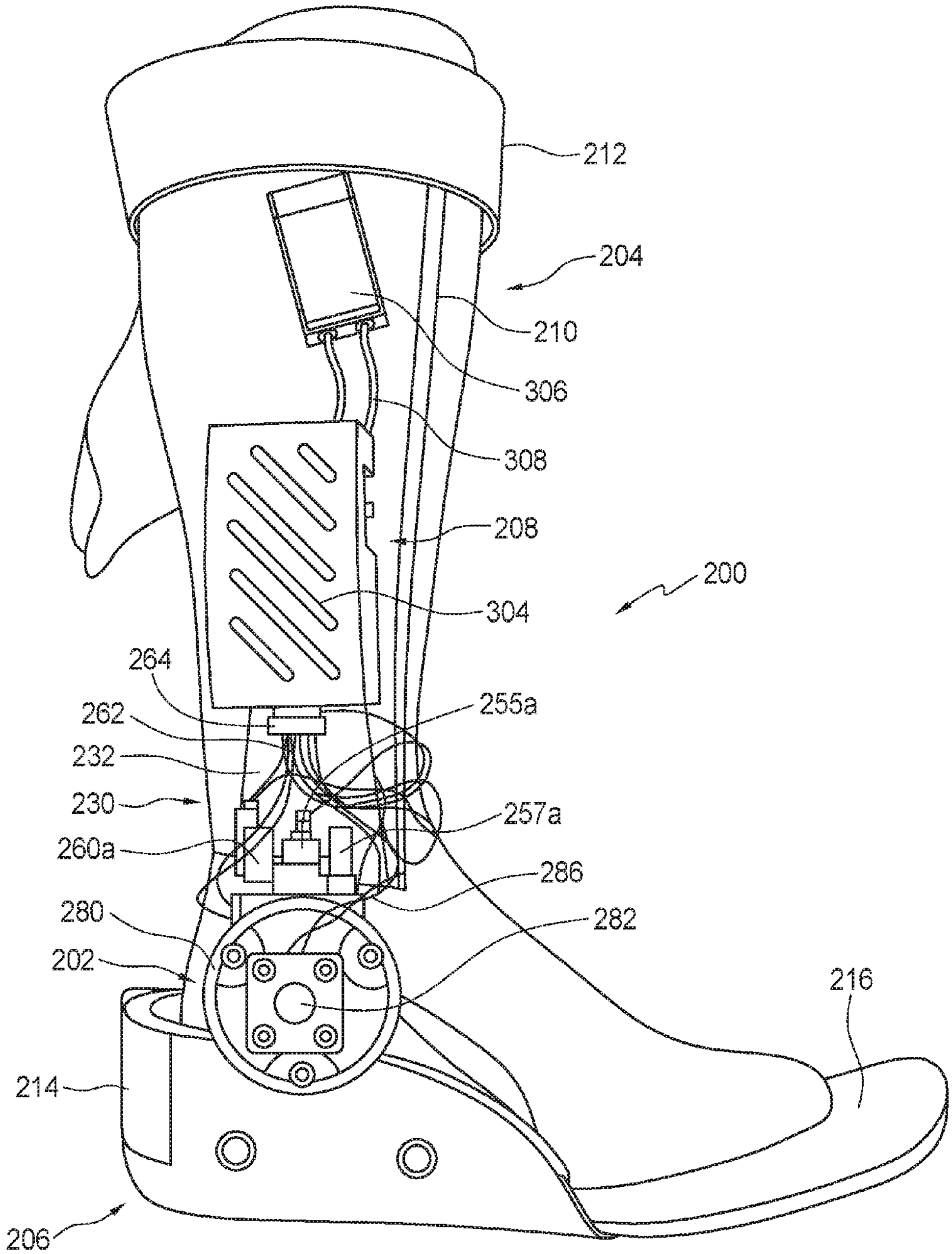

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FIG. 15

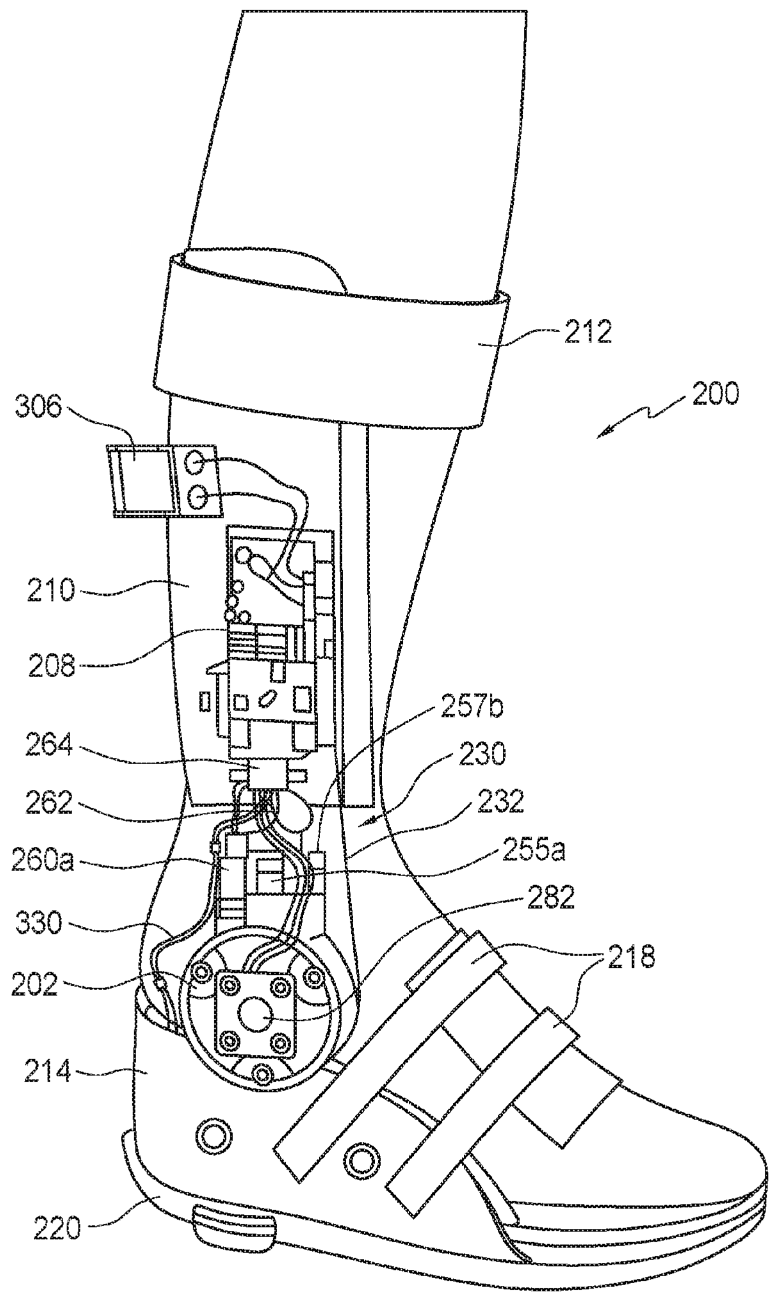
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FIG. 16

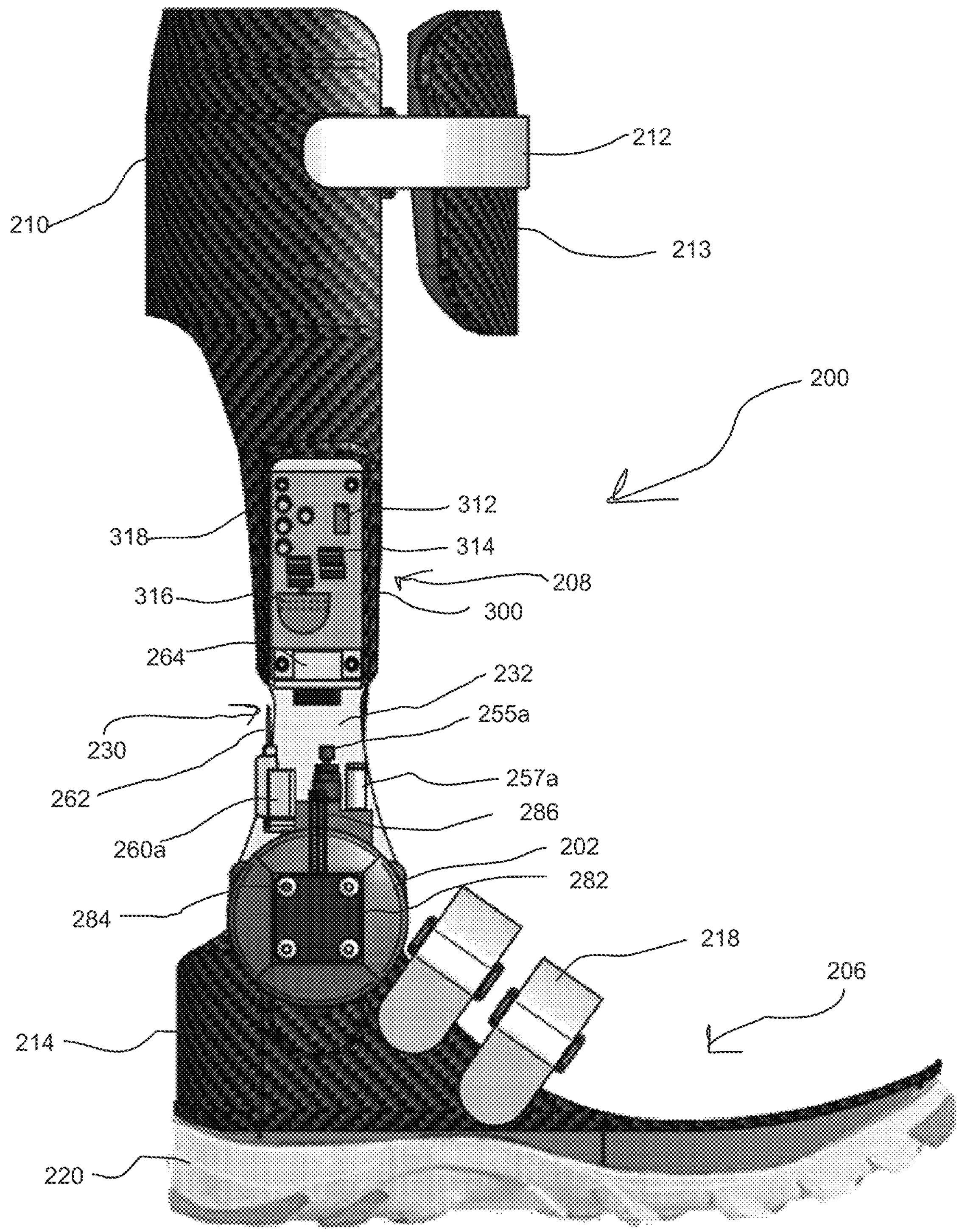
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FIG. 17

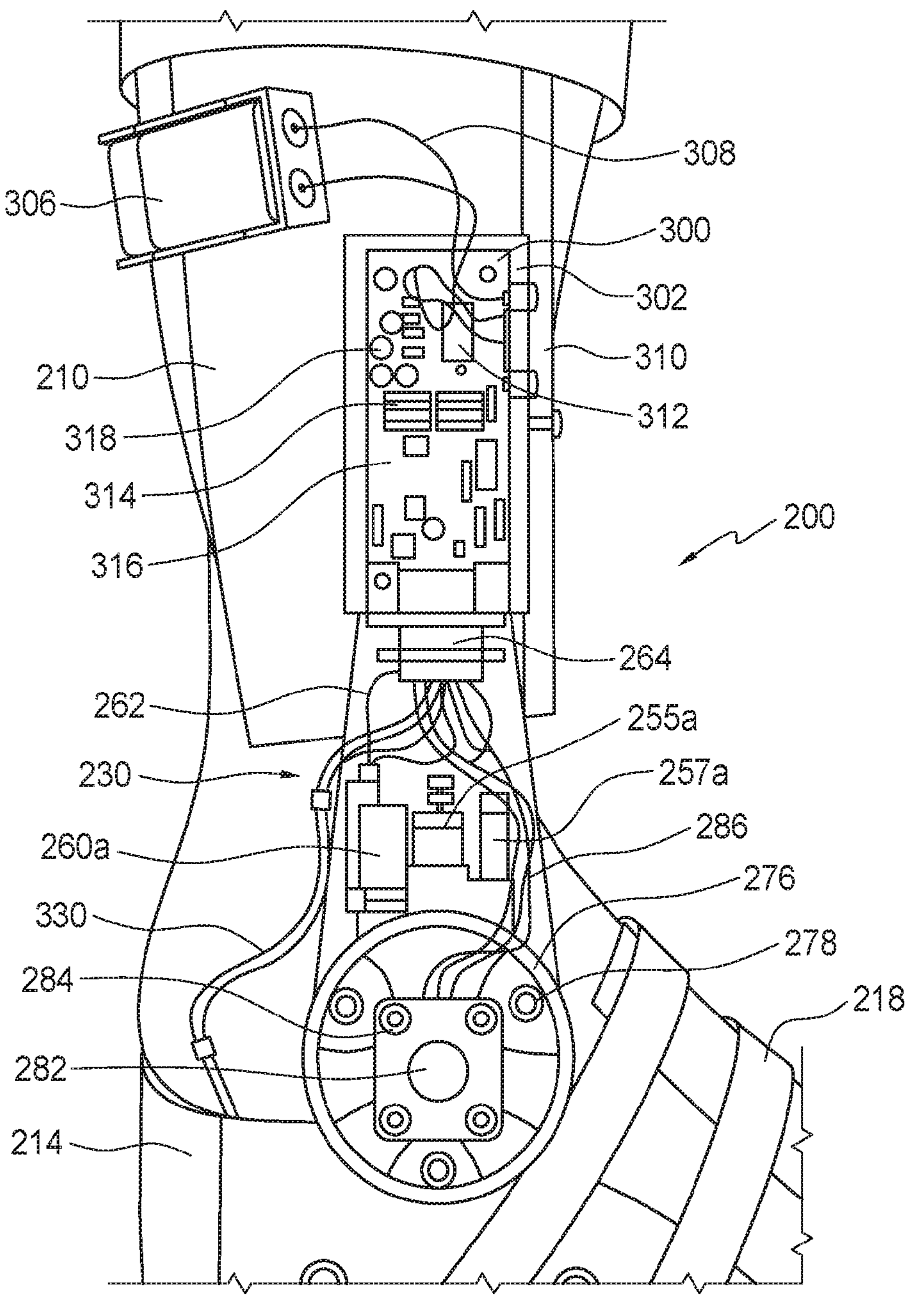
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FIG. 18

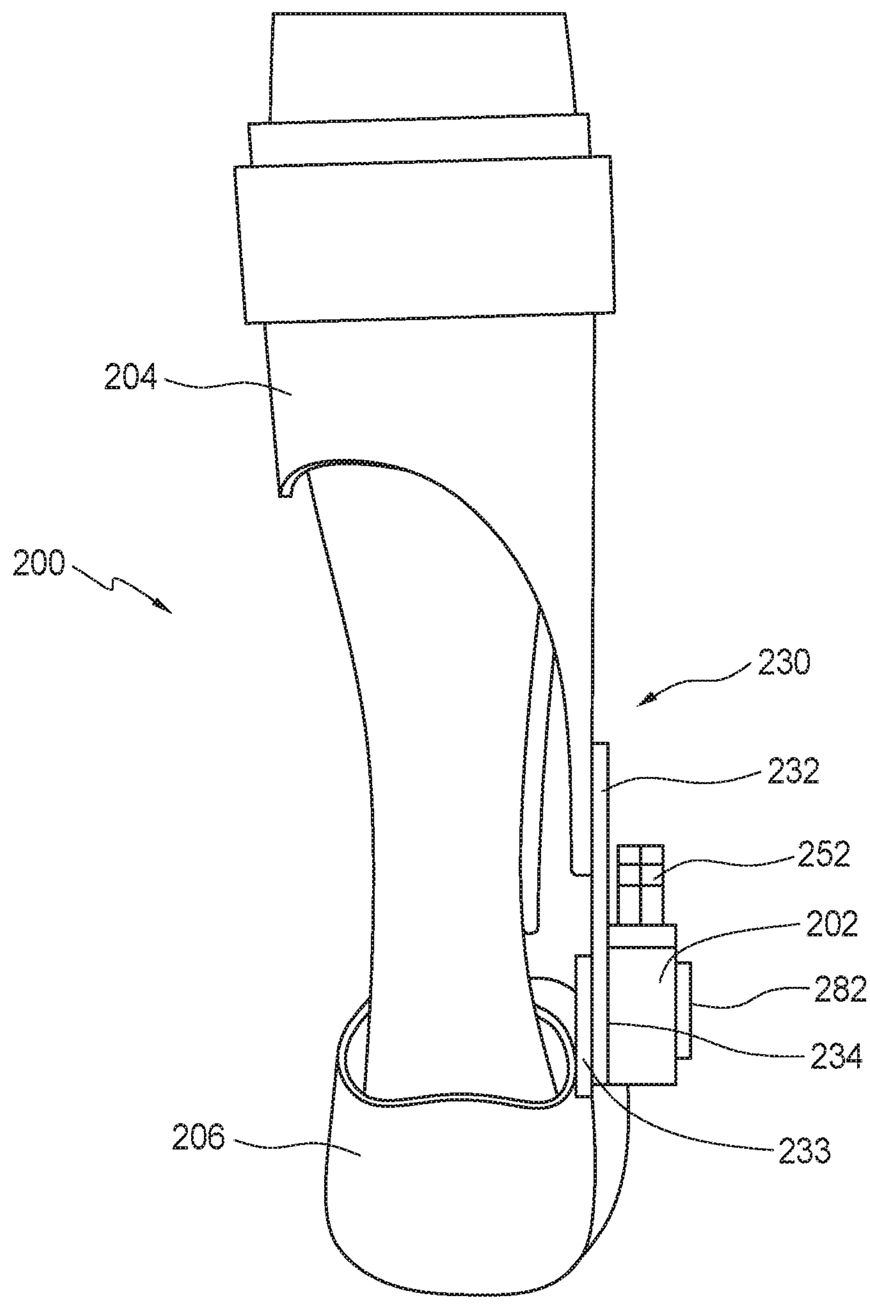
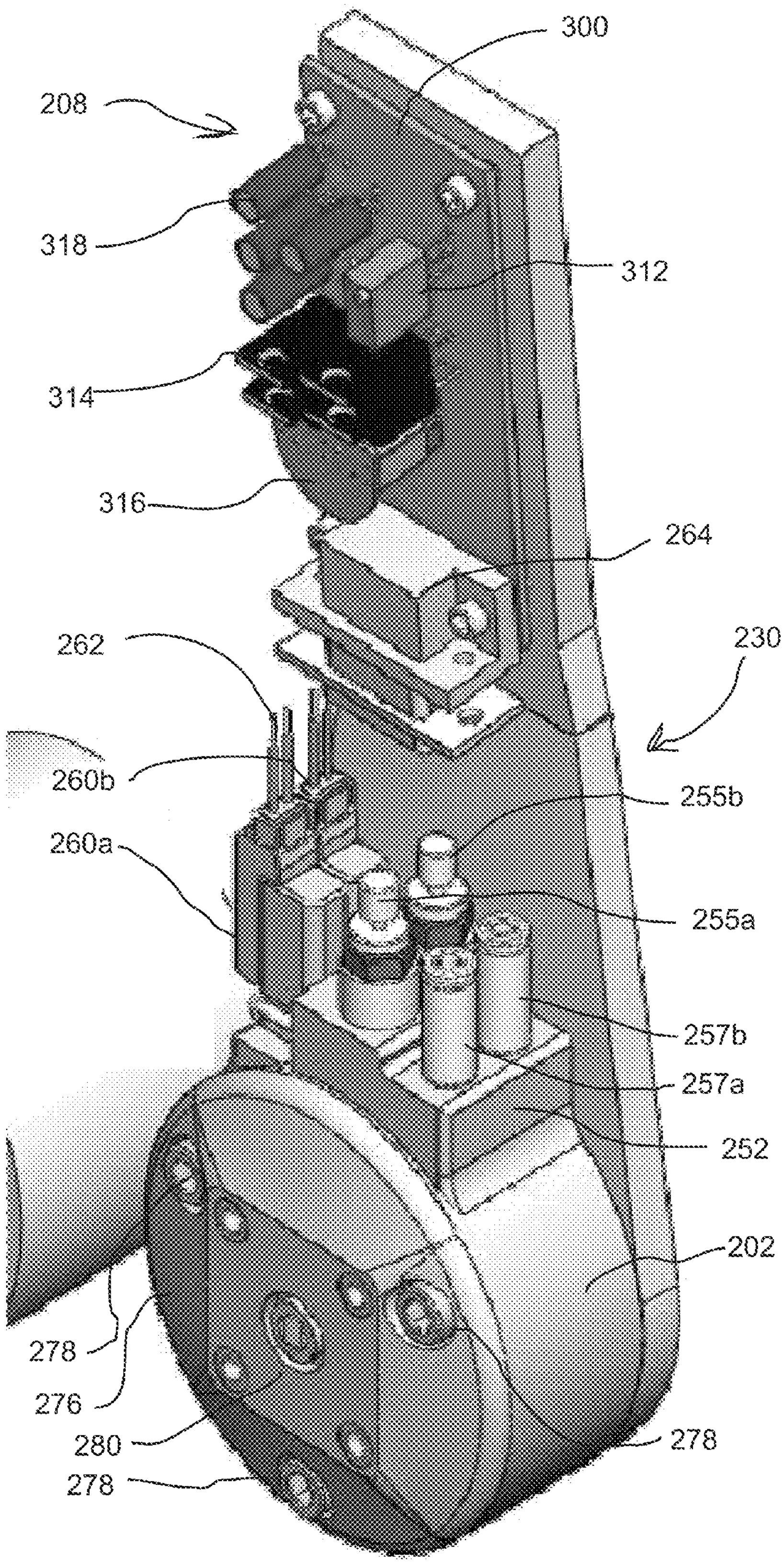


FIG. 19

FIG. 20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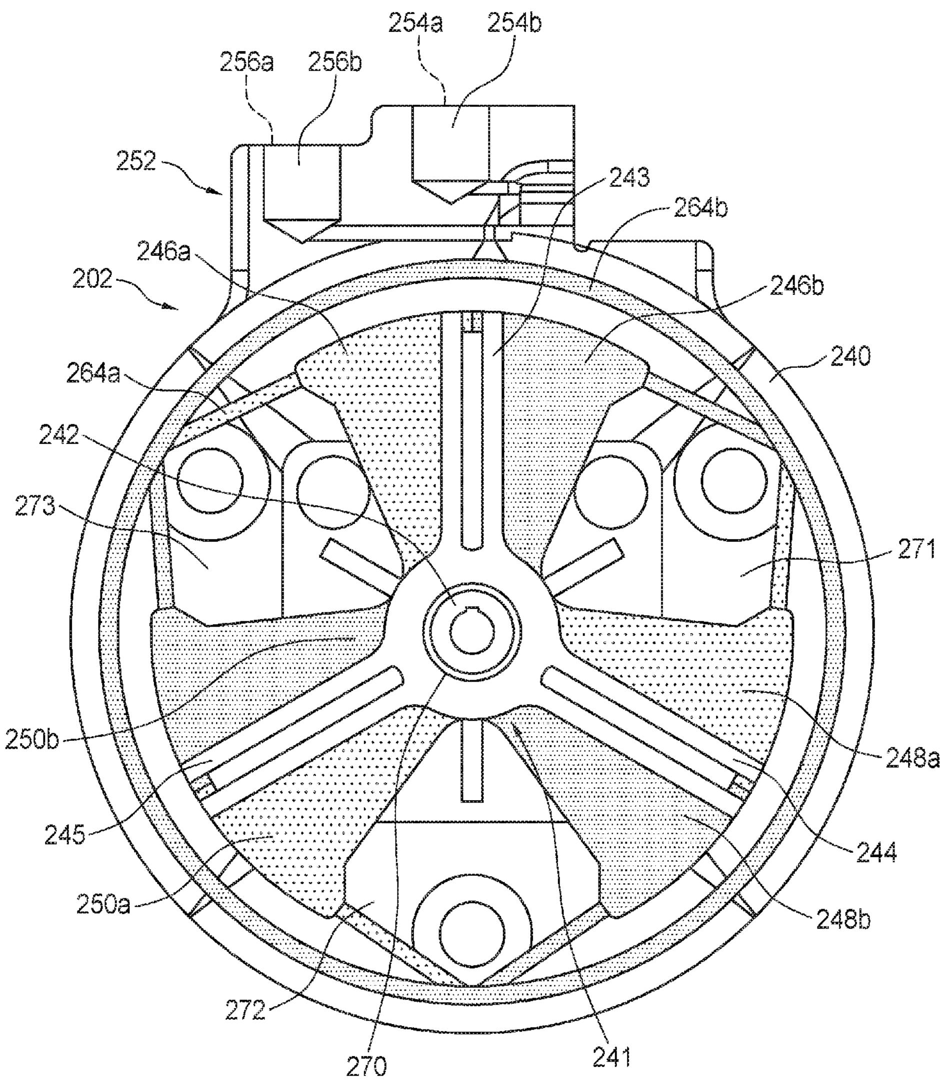
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FIG. 21

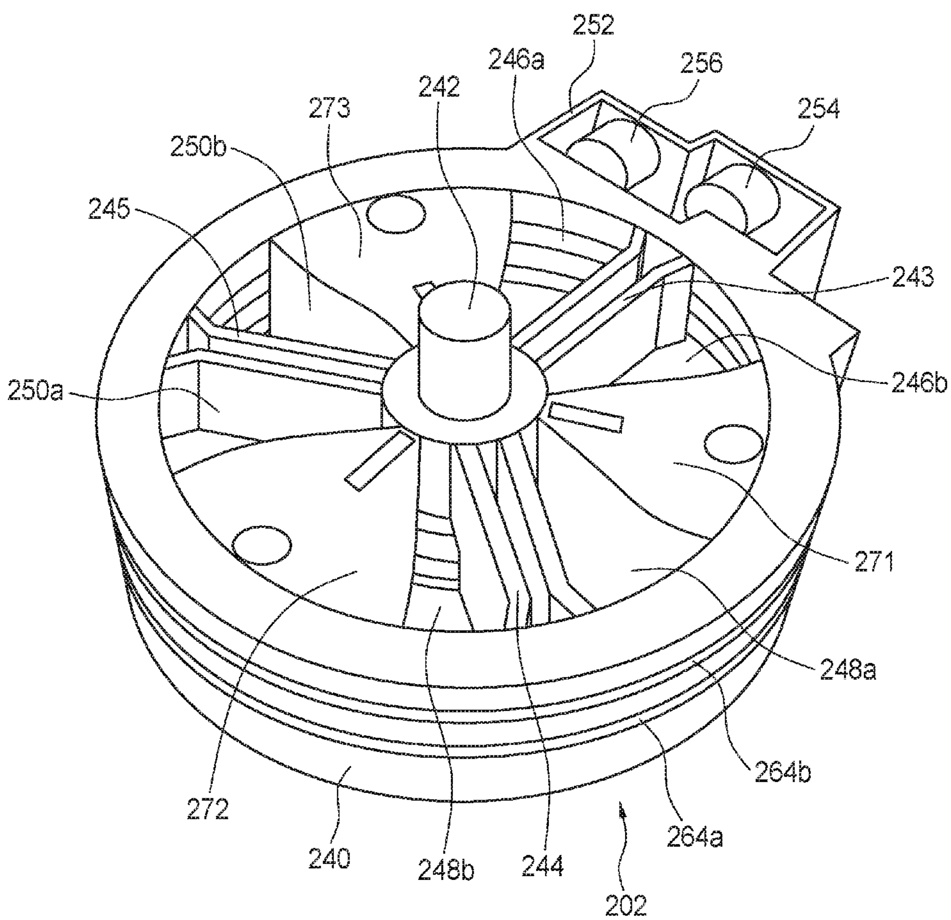
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FIG. 22

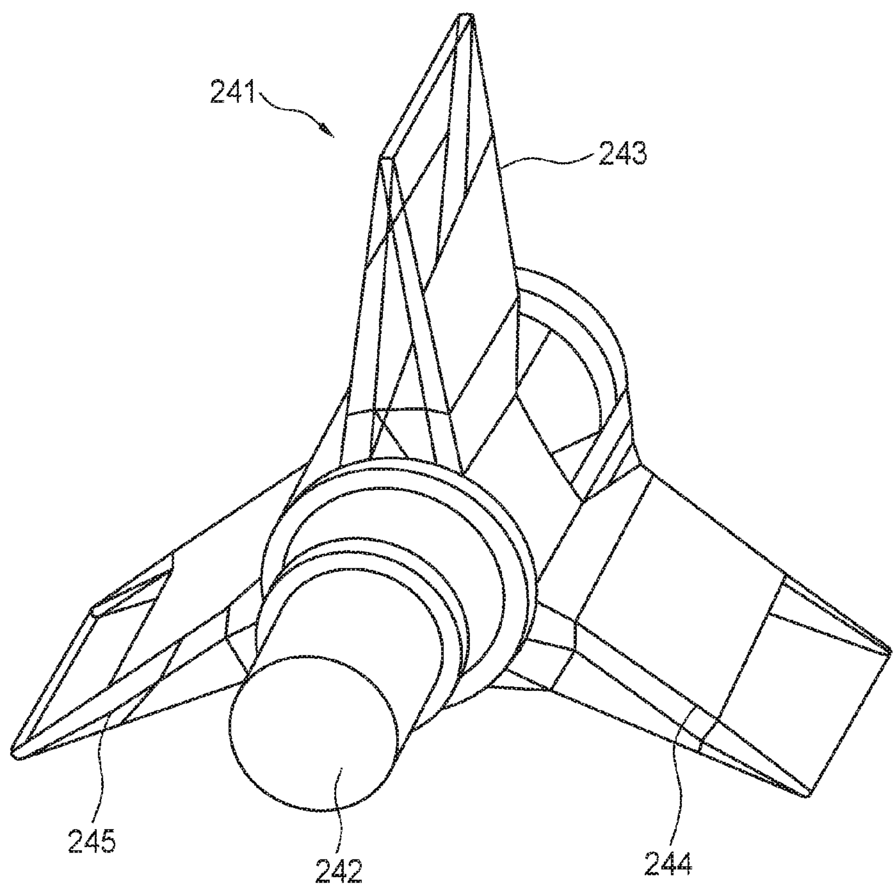

FIG. 23

PORTABLE ACTIVE PNEUMATICALLY POWERED ANKLE-FOOT ORTHOSIS

PRIORITY CLAIM

This application claims the benefit of U.S. Provisional Application Ser. No. 61/452,523, filed Mar. 14, 2011, under 35 U.S.C. §119. This application is a continuation-in-part of U.S. patent application Ser. No. 12/898,519, filed Oct. 5, 2010.

STATEMENT OF GOVERNMENT INTEREST

This invention was made with Government support under Contract No. 0540834 awarded by the National Science Foundation. The Government has certain rights in the invention.

FIELD OF THE INVENTION

A field of the invention is orthotics.

BACKGROUND OF THE INVENTION

During normal gait, the ankle joint, shank, and foot play important roles in all aspects of locomotion, including shock absorption, stance stability, energy conservation and propulsion. For example, FIG. **1** shows foot **10** and ankle joint **12** movement during part of normal gait. A gait cycle is typically defined from the initial contact of the heel **14** to the following heel contact. At the initiation of the gait cycle, impact forces are dissipated when energy is absorbed by the soft tissues at the heel **14** as the foot **10** comes into contact with the ground **16**. Additionally, the muscles and tendons of the ankle joint complex act as an energy-dissipating brake to control the deceleration of the foot **10** before full contact with the ground **16** at foot-flat. The ankle joint complex also helps to maintain stability during stance phase. This is particularly important during the single support part of the stance phase, when the contralateral limb is swinging and only one limb is supporting the body. In addition to providing stability, energy is stored in the stretching of tendons and muscles of the ankle joint complex when the shank **18** pivots. The plantarflexion torque generated at the ankle **12** at push-off results in the highest power output for any joint during walking and is the primary source of power for forward propulsion.

Pathology or injury that affects the ankle joint can significantly impact quality of life by impairing some or all functional aspects of gait. Both dorsiflexor and plantarflexor muscle groups of the ankle-foot complex are critical to normal walking, and undesirable compensatory gait patterns result from weakened or impaired muscles of either type. Other causes of lower limb gait deficiencies include, but are not limited to, trauma, incomplete spinal cord injuries, stroke, multiple sclerosis, muscular dystrophies, and cerebral palsy.

The dorsiflexors (e.g., shin muscles) lie anterior to the ankle joint and include the tibialis anterior, extensor digitorum longus, and extensor hallucius longus. Weak dorsiflexors affect both stance and swing phases of gait, causing clearance issues during swing phase and uncontrolled deceleration of the foot at initial stance. Swing is affected because the foot does not effectively clear the ground due to weak or absent dorsiflexor muscles, which results in a steppage-type gait pattern that is commonly called foot drop. Steppage gait is a compensatory walking pattern characterized by increased knee and hip flexion during the swing phase so that the toe clears the ground during walking. The weak or absent dorsiflexors also prevent the controlled deceleration of the foot shortly after heel strike. This lack of control results in an often audible foot slap that impacts stance initialization.

The plantarflexors (e.g., calf muscles) lie posterior to the ankle joint and include the gastrocnemius, soleus, and the peroneal and posterior tibial muscles. From heel strike to middle stance, the ankle plantarflexors concentrically contract to stabilize the knee and ankle and restrict forward rotation of the tibia. At the end of stance, the plantarflexors concentrically contract and generate torque that accelerates the leg into swing and contributes to forward progression.

Weak plantarflexors primarily affect stance phase by reducing stability and propulsive power of the individual, particularly during limb support. Individuals with impaired ankle plantarflexors compensate by reducing walking speed and shortening contralateral step length. Reduced walking speed results in a corresponding reduction in torque needed for forward progression. The shortened contralateral step is thought to increase stability by limiting anterior movement of the center of pressure with respect to the ankle. Impaired individuals may maintain a fast walking pace by using their hip flexors to compensate for weak plantarflexor muscles.

Ankle foot orthoses (also referred to herein as orthoses or AFOs) can be used to ameliorate the impact to gait of impairments and injuries to the lower limb neuromuscular motor system. AFOs can be used for rehabilitation, diagnostic, or training devices, for example, to assist walking function, direct measurement of joint motion and force, and to perturb gait. Existing technologies for AFOs include passive devices with fixed and articulated joints with or without spring assist, semi-active devices that modulate the spring or damping about the joint, and active devices with various technologies to produce power and to move the joint.

Passive devices generally limit the foot angle to the neutral position (i.e., 90° between leg and foot), which can produce an unnatural gait but prevents further damage or injury and provides limited mobility to people that use them. Passive orthoses do not provide direct assistance during the propulsive phase of gait. Commercial passive devices improve gait deficiencies using motion control. The control of passive AFO elements relies on the activation of springs, valves, or switches in an open-loop manner as the individual walks. This type of AFO has limited robustness and does not adapt to changing walking conditions.

Semi-active devices can store energy, such as in a spring, and provide braking assistance but do not add energy into the system to aid propulsion. Active devices provide assistance in propulsive movements necessary for normal gait. Particular active devices that provide assistance in propulsive phases of gait have been developed for clinical or laboratory settings and are tethered to power sources. Such devices cannot be used outside the clinic or laboratory. Typical active and semi-active devices use large electromechanical actuators that are cumbersome and unattractive.

Compactness and weight are critical to daily use, and current commercial orthoses are all passive as a result. These include passive articulated or non-articulated orthoses, which are made from materials including metal and leather systems, thermoplastics, composites, and hybrid systems. Traditional metal and leather systems have articulated hinge joints with various types of mechanical steps used to limit motion. Some orthoses include springs to resist or assist movement. Common passive devices inhibit motion at undesirable times. Common and more newly developed semi-active devices can also stop or resist motion at undesirable points and only store energy provided by a user, which may not be ideal for treating many gait impairments.

SUMMARY OF THE INVENTION

Embodiments of the present invention provide, among other things, a portable active pneumatically-powered ankle foot orthosis. An example device comprises a lower leg mount and a foot bed pivotally coupled to the lower leg mount at or proximate to an ankle position. A pneumatically powered rotary actuator is configured to receive power from a portable (e.g., wearable) fluid power source and provide controlled force and/or resistance to aid or inhibit relative rotation of the foot bed and the lower leg mount. Embedded sensors are used to provide feedback from the orthosis to actively assist gait of a user.

Additional embodiments of the invention provide a portable active pneumatically powered ankle foot orthosis comprising a lower leg mount, a foot bed pivotally coupled to the lower leg mount at or proximate to an ankle position, and at least one sensor for determining a phase of a user's gait. A pneumatically powered rotary actuator is coupled to the leg mount and to the foot bed. The rotary actuator is configured to receive power from a wearable fluid power source and to provide controlled force and/or resistance to aid or inhibit relative rotation of the foot bed and the lower leg mount. At least one valve is integrated with the rotary actuator. A controller is provided for receiving data from the at least one sensor and controlling the pneumatically powered rotary actuator by controlling the at least one valve to actively assist gait of a user. Preferably, the actuator and the controller are both disposed on a support structure to provide a subassembly integrating the actuator, controller, and valve (s). This subassembly can be coupled to the leg mount.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows motion of a heel and an ankle joint during a portion of normal gait;

FIG. **2** is a side elevation view of an active ankle foot orthosis, according to an embodiment of the present invention;

FIG. **3** is an exploded rear perspective view of the active ankle foot orthosis of FIG. **2**;

FIG. **4** is an exploded front perspective view of the active ankle foot orthosis of FIGS. **2-3**;

FIG. **5** shows the active ankle foot orthosis of FIGS. **2-4** worn around a leg of a user and coupled to a fluid power source;

FIG. **6** shows interactivity of various components of the active ankle foot orthosis during operation, according to a method of the present invention;

FIG. **7** shows phases during a normal gait cycle;

FIG. **8** shows an example method for determining weight acceptance and single limb support and for controlling the active ankle foot orthosis;

FIG. **9** shows an example method for determining push-off and for controlling the active ankle foot orthosis;

FIG. **10** shows an example method for determining limb advancement and for controlling the active ankle foot orthosis;

FIG. **11** shows an example control system and method for the example orthosis;

FIG. **12** shows an example method for tuning dorsiflexor assist;

FIG. **13** shows an example method for tuning operational timing;

FIG. **14** shows a control system and method according to another embodiment of the invention;

FIG. **15** is a side view of a portable powered ankle foot orthosis device according to another embodiment of the present invention;

FIG. **16** is a perspective view of the orthosis device of FIG. **15**, with a cover for a controller removed for illustration;

FIG. **17** is a side view of components of the orthosis device of FIGS. **15-16**, with the cover for the controller removed, and the battery omitted;

FIG. **18** is a side view of the orthosis device of FIGS. **15-17**, including signal connections;

FIG. **19** is a rear perspective view of the orthosis device of FIGS. **15-18**;

FIG. **20** is a perspective view of a subassembly for the orthosis device of FIGS. **15-19**, with connections removed for clarity;

FIG. **21** is a rear view of a rotary actuator according to an embodiment of the present invention, with the back plate removed for clarity;

FIG. **22** is a rear perspective view of the rotary actuator of FIG. **21**; and

FIG. **23** is a perspective view of a triple vane for the rotary actuator of FIGS. **21-22**.

DETAILED DESCRIPTION

Embodiments of the invention provide a portable active pneumatically powered ankle foot orthosis. Example devices of the invention are pneumatically powered by a self-contained and portable (e.g., wearable) fluid power source, such as a container (e.g., bottle, cylinder, cartridge, etc.) of CO_2 or other suitable fluid. CO_2 containers that may be used include, as nonlimiting examples, containers used in the power tool industry. The CO_2 or other fluid container can be worn on a belt or another area of the body. The fluid power source is coupled to a rotary actuator at or proximate to the ankle joint that is controlled by an on-board controller, e.g., a microcontroller having a microprocessor and memory. The torque generated by the actuator can be used for both motion control of the foot and to provide supplemental torque for the individual during gait.

A compact and lightweight structure attaches to the lower leg of a user, for instance around the leg, to provide a lower leg mount, and a pivotally attached foot bed attaches to the user's foot. The foot bed includes at least one sensor for determining a stage during gait, such as one or more force sensors that communicate with the on-board controller. A rotational sensor preferably monitors the angle between foot and lower leg and also communicates with the on-board controller. Pressure regulators can be used in example embodiments to manage the torque produced by the rotary actuator, and valves can be used to control the actuator by directing the fluid power to the actuator. Control and sensing of the actuator are accomplished through use of the force and/or angle sensor, as well as the on-board controller. In an example operation, the pneumatically powered rotary actuator provides active assistance under direction of the on-board controller via fluid control valves based upon information that the controller receives from the force sensors to provide active ankle torque assistance, either dorsiflexor torque or plantarflexor torque.

Advantageously, in preferred embodiments, the fluid power source can be a low power source, e.g., having a power of 10-100 W. Example devices have a weight of about 2 kg or less excluding the power source. It is also contemplated for devices to have a weight of 1 kg or less. The power source is preferably belt worn and adds about an additional 1.2 kg for an example CO_2 portable bottle, but can provide a significant operational range; as a nonlimiting example, ~40 minutes of continuous use, and longer depending upon conditions, level of assistance, and amount of use. Operating temperature preferably is below 100° F. Use can be extended easily by simply inserting a recharged gas cylinder or other changeable power source.

A preferred embodiment orthosis using a low power CO_2 fluid power source includes a rotary actuator that provides up to about 10 Nm of torque, though rotary actuators providing more than 10 Nm are also contemplated, such as for providing more than partial assist. A compact, lightweight lower leg and foot bed structural shell of carbon fiber or other suitable material can be custom molded to an individual user to be unobtrusive and work with normal clothing and footwear. A small battery or other suitable power source, such as but not limited to a 9V battery, 2×AA batteries, or equivalent secondary battery, provides power for the on-board controller. In an example fitting session, the controller includes software (or firmware or hardware) that can receive information about the individual and the individual's condition, and the amount of assistance in propulsive gait and in braking can be tailored by adjustment of control parameters. While an example orthosis of the invention can rely upon a uniform resistive force for braking, example controllers and actuators can also provide active braking.

The active nature of example devices of the invention provides the flexibility to assist both the plantarflexor and dorsiflexor muscle groups in approaching their functional objectives during gait. An example rotary actuator can control the velocity of the foot during initial contact to prevent foot-slap, provide torque at the end of stance for propulsion, support the foot in the neutral (or 90°) position during swing to prevent foot-drop, and allow free range of motion during the rest of the cycle. Timing and magnitude of the assistance can be determined uniquely for each user through the electronic controller and/or mechanical adjustments. For example, tuning can be accomplished using feedback from the sensors on the device, measurements from lab equipment, observation from the investigators, and/or feedback from the participant to determine a subject specific control scheme that is downloaded to the microprocessor embedded in the example on-board controller.

An example operation assists impaired gait by determining a phase in a gait cycle and providing controlled resistance or assistance. For example, at heel strike, an example orthosis can control forefoot velocity to prevent foot slap by providing eccentric dorsiflexor assistance. At the end of stance, the example device can provide modest assistive torque for propulsion and stability by providing concentric plantarflexor assistance. During swing, the example device can support the user's foot in the neutral position during swing to prevent foot drop by providing concentric dorsiflexor assistance. During other parts of the gait cycle, the example device can allow free range of motion.

Preferred embodiments will now be discussed with respect to the drawings. The drawings include schematic figures that may not be to scale, which will be fully understood by skilled artisans with reference to the accompanying description. Features may be exaggerated for purposes of illustration. From the preferred embodiments, artisans will recognize additional features and broader aspects of the invention.

FIGS. **2-5** show a portable, active ankle foot orthosis device **20** according to an embodiment of the present invention. The device **20** includes a lower leg or tibial mount component or assembly (lower leg mount) **22** and a foot bed component or assembly (foot bed) **24** pivotally coupled (e.g., attached) to one another at or proximate to an ankle position of a user wearing the device. In the example device **20**, the lower leg mount **22** and the foot bed **24**, which serve as structural elements of the device are pivotally coupled via a pneumatically powered rotary actuator **26** at or proximate to an ankle position; e.g., the ankle joint. A free motion ankle hinge joint connects the foot bed **24** to the leg mount **22** on the medial aspect, though this is not required for all devices. A particular, nonlimiting example pneumatic actuator **26** is a dual-vane bidirectional rotary actuator (e.g., CRB2BW40-90D-DIM00653; SMC Corp of America, Noblesville, Ind., USA).

The actuator **26** is configured to receive power from a portable fluid power source and provided controlled force and/or resistance to aid or inhibit relative motion between the lower leg mount **22** and the foot bed **24**. As shown in FIG. **5**, a nonlimiting example portable fluid source is a CO_2 (or other suitable fluid) container, e.g., bottle **28**, which, for example, may be worn on a belt or elsewhere on a user. A nonlimiting example CO_2 container is a 255 g portable compressed liquid CO_2 bottle (JacPac J-6901-91; Pipeline Inc., Waterloo, Calif.) worn by the user on the waist. Providing the portable fluid power source **28** allows untethered powered assistance. An on-board controller **30**, e.g., a microcontroller, integral to the device **20** (that is, coupled to and movable with the device, as opposed to being separated from or tethered to the rest of the device) accepts data input from measuring devices for determining a stage of gait. Nonlimiting examples of such measuring devices include force sensors (e.g., force sensitive resistors; a particular nonlimiting example is a 0.5" circle obtained from Interlink Electronics, Camarillo, Calif.), for instance a fore foot (or front, or toe) sensor **32** and a rear sensor **34**. A rotary sensor **36**, which in the example device **20** is a belt drive potentiometer, preferably is also provided to control the actuator **26** during active assistance of the user.

The lower leg mount **22** (which generally refers to any structure suitable for at least partially holding and supporting a part of a user's lower leg or shank during gait) in the example device **20** includes a cuff **40**, or all or part of a sleeve, configured for accommodating and at least partially supporting a lower leg of the user. The cuff **40** should be as lightweight as possible, while providing sufficient support for the lower leg and for any components of the device **20** that are attached thereto. For example, in the device **20**, the controller **30** is attached to a rear portion of the lower leg mount **22**. The lower leg mount **22** preferably includes a light, fairly rigid inner frame, e.g., carbon fiber or carbon composite, light metal, or plastic, which is lined and padded for user comfort. A strap **42** fits a front plate **44** to a shin of the user (e.g., see FIG. **5**) and can be tightened around the lower leg after the user places his/her foot in the foot bed **24**, to secure the cuff **40** and the front plate **44** around the lower leg. The front plate **44**, as with the cuff **40**, can include a rigid inner frame (e.g., carbon fiber or carbon composite, light metal, or plastic) that is lined and padded. It is also contemplated that the leg mount **22** could have a small diameter (e.g., ~18 cm ID cylinder) for fitting inside a user's pants leg, though this is not required in all embodiments.

The foot bed **24** in the example device **20** (generally, any structure suitable for at least partially holding and supporting a part of a user's foot during gait), which can be configured for a right or left foot and be sized according to an individual user, includes a base **45** having an inner frame of a sturdy, lightweight material (e.g., carbon fiber or carbon composite (such as but not limited to pre-impregnated carbon composite laminate material), light metal, or plastic), which is preferably lined and/or padded. A bottom plate **46** of the foot bed **24** supports the user's foot, which can be held within the foot bed **24** by one or more straps **48**. The straps **42**, **48** may be any suitable strap, including but not limited to straps fastened by suitable fasteners, e.g., buckles or hook-and-loop fasteners (such as VELCRO® fasteners). A sole **49**, preferably with suitable padding, is provided underneath the bottom plate **46** to provide an interface with the ground and for cushioning during walking. As a nonlimiting example, a standard shoe sole could be used. The foot bed **24** can vary in terms of, as nonlimiting examples, height of the heel relative to the metatarsal heads, angle (pitch) of a toe section, etc. It is also contemplated that the foot bed **24** could be configured to fit inside a (e.g., modified) running or walking shoe, with the sole **49** being provided by the sole of the shoe.

For coupling to the actuator **26** and to the foot bed **24**, the lower leg mount **22** also includes a pair of laterally opposed rigid lower members such as struts **50**, **51** which preferably are made of a rigid material (e.g., a light metal). The struts **50**, **51** may be integrally formed with the inner frame of the lower leg mount **22**, or may be separate components rigidly coupled to the inner frame, as shown in FIGS. **2-4**. One of the struts **50** couples the leg mount **22** to the actuator **26**, while the other **51** preferably couples the leg mount to the foot bed **24** via the free motion ankle hinge joint. Each of the struts **50**, **51** is preferably configured to couple the lower leg mount **22** to the foot bed **24** while rigidly supporting the lower leg mount such that relative movement of the lower leg mount and the foot bed (e.g., during operation of the actuator) does not alter the structure and leg support provided by the lower leg mount. Also, one or both of the struts **50**, **51** can be used in particular example embodiments to support other components of the device, alone or in combination with the inner frame of the lower leg mount **22**. In other embodiments, only one of the struts (e.g., strut **50**) is provided, and the other strut (e.g., strut **51**) and the separate free motion ankle hinge is omitted.

Similarly, the foot bed **24** includes a pair of laterally opposed rigid upper members such as extensions **54**, **55** (best seen in FIGS. **2** and **4**), which extend upwardly from the base **45** for rigidly coupling to the actuator **26** and to the lower leg mount **22**. The extensions **54**, **55** may be integrally formed with the base **45** or may be fixedly coupled to the base. One of the extensions **54** couples the foot bed **24** to the actuator **26**, while the other extension **55** preferably couples the foot bed to the strut **51** on the lower leg mount **22** via a suitable pivotal attachment, such as the free motion ankle hinge joint. As with the struts **50**, **51**, it is also contemplated that the extension **55** can be omitted in embodiments where the lower leg mount **22** and the foot bed **24** are pivotally coupled only via the actuator **26**. In an example embodiment to provide the free range joint, the strut **51** includes a rotational coupling such as a pin **56**, which is inserted into an aperture of the extension **55** for allowing relative rotation of the strut and the extension. However, it will be appreciated that other rotational couplings may be used.

The example pneumatically powered rotary actuator **26** shown in FIGS. **2-4** is a rotary actuator similar to that used for conveyor systems. However, the invention is not to be limited to the particular actuator **26** shown. For example, more compact designs, lighter designs, more efficient designs, etc. can be used, as will be appreciated by those of ordinary skill in the art. In an example embodiment, fluid control for the actuator **26** is provided by directing flow of the fluid with valves **60**, e.g., two solenoid valves (e.g., VOVG 5V, Festo Corp., Hauppauge, N.Y.), coupled to the controller **30**. These valves allow the direction of the torque to be switchable between dorsiflexor and plantarflexor. A pair of fluid pressure regulators **62**, **63** (fluid regulators) can also be provided to manage the force produced by the actuator. For example, the fluid pressure regulator **62** can be on or proximate to the fluid power source **28** (FIG. **5**), such as but not limited to a pressure regulator provided on the fluid power source itself. The fluid pressure regulator **62** modulates plantarflexor torque for propulsion assistance. The additional fluid pressure regulator **63** (e.g., LRMA-QS-4; Festo Corp.; Hauppage, N.Y., USA), which can be disposed between the valves **60** and the actuator **26**, can be used to modulate dorsiflexor torque for foot support during swing.

As shown in FIG. **2** particularly, the valves **60** and the additional fluid regulator **63** can be supported by the strut **50** of the lower leg mount **22**, though it is also contemplated that the valves and/or fluid regulator can be supported by the frame of the lower leg mount, or by other parts of the device **20**. The valves **60** and the additional fluid regulator **63** can be coupled, e.g., attached, to the strut **50** or other portions of the lower leg mount **22** or elsewhere on the device **20** by any suitable devices or methods, including but not limited to mechanical fasteners and/or adhesives. An alternative pneumatically powered rotary actuator can include electronically controlled fluid control for direct control by the on-board controller **30**, and in this case separate valves and/or a fluid regulator may not be necessary. It is also contemplated that other valves, e.g., more compact and/or lighter valves, may be used in place of the valves **60** to make the overall device **20** lighter and/or more compact.

So that the valves **60** can selectively control fluid flow to the example actuator **26**, fluid couplings, e.g., lines **64**, **65**, **66**, couple the actuator and the valves. Particularly, fluid line **64** is disposed between an output **72** of one of the valves **60** and an input **70** of the actuator **26**, directly coupling the valve and the actuator. Additionally, fluid line **65** is disposed between an output **68** of another of the valves **60** and an input **74** of the pressure regulator **63**, and fluid line **66** is disposed between an output **76** of the pressure regulator and another input **78** of the actuator, providing an indirect fluid coupling between the valves **60** and the actuator **26**. The fluid lines **64**, **65**, **66** may be any suitable opening sealed with fluid tubing, and the inputs **70**, **74**, **78** and the outputs **68**, **72**, **76** may be any suitable fluid caps or seals with passages for the fluid lines.

It is preferred that the fluid lines **64**, **65**, **66**, inputs **70**, **74**, **78**, and the outputs **68**, **72**, **76** are of a lightweight material, such as lightweight tubing material, to minimize weight of the overall device **20**. Those in the art will appreciate that various individual or combined components may be used for the fluid lines **64**, **65**, **66**, inputs **70**, **74**, **78** and outputs **68**, **72**, **76**. A nonlimiting example weight for the device **20**, without the CO_2 or other fluid container **28**, is 1.9 kg.

Inputs **80**, **82** of the valves **60** (suitably sealed and/or capped) are in turn coupled to an output of the fluid power source, e.g., the CO_2 container **28**. In a nonlimiting example embodiment, the output of the CO_2 container **28** is input to the first fluid regulator **62** and then output via line **84** (FIG.

5) to a splitter **85** having outputs coupled to suitable fluid lines **86** connecting the outputs to the inputs **80**, **82** of the valves **60**. Fluid lines may be similar to the fluid lines **64**, **65**, **66** used for other connections, or may be of a different type. Artisans will appreciate that various fluid lines, splitters, seals, caps, etc. may be used. The example CO_2 container is preferably belt worn and is relatively light (e.g., about 1.2 kg for an example CO_2 portable bottle), but can provide an operational range suitable for untethered operation of the device **20** (e.g., about 40 min. continuous use, longer depending upon conditions, level of assistance, and amount of use). In a nonlimiting example, plantarflexor regulated torque is ~10 Nm at 90 psi, and dorsiflexor regulated torque is ~3 Nm at 30 psi. Use can be extended easily by inserting a recharged gas cylinder or other power source.

The example solenoid valves **60** are configured to be selectively controlled by the on-board controller **30**. In an example embodiment, the direction of the torque can be switched between dorsiflexor and plantarflexor by controlling the two solenoid valves **60**. Suitable leads **88** electrically couple an input/output connection **90** of the on-board controller **30** to the valves **60** for operating the solenoids.

As best seen in FIG. **3**, the example on-board controller **30** includes an outer housing **92** containing a circuit board **94**. The housing **92** can include a curved outer surface for coupling to the lower leg mount **22** while reducing total device volume. Attachment of the housing **92** to the device, e.g., to the lower leg mount **22**, can be accomplished using any suitable method or device, including mechanical devices and/or adhesives. A cover **95**, which may be vented, encloses the housing **92**.

The circuit board **94** includes a microprocessor **96** (with suitable memory), power source (as nonlimiting examples, a 9V battery, 2×AA batteries, etc.) **98**, an input (of the input/output connection **90**) for electrically coupling to the sensors **32**, **34**, **36**, and an output for coupling to the valves **60**. A nonlimiting example controller is eZ430-F2013 microcontroller, Texas Instruments, Dallas, Tex. Example controllers **30**, including the microprocessor **96**, the circuit board **94**, etc., can be commercially obtained or custom made to reduce size, weight, power requirements, etc. As a nonlimiting example, a customized chip may be provided in place of one or more components. Coupling between the on-board controller **30** and the sensors **32**, **34**, **36** can be wired or wireless. The microcontroller preferably is configured, e.g., programmed, via suitable hardware, firmware, or software, to control the valves **60** and thus the actuator **26** based on input from one or more of the sensors **32**, **34**, **36**, according to methods of the present invention.

The sensors **32**, **34**, **36** are disposed in or on the device **20** to allow feedback for input to the controller **30**. In an example embodiment the rear sensor **34** is disposed in or on the base **45**, foot plate **46**, sole **49**, or elsewhere in or on the foot bed **24** to receive pressure information at or near the heel of the foot bed. Similarly, the fore foot sensor **32** is disposed in or on the base **45**, foot plate **46**, sole **49**, or elsewhere, and preferably is placed under the metatarsal head of the foot bed, to receive pressure information near the front of the foot bed, e.g., at or near the toe of the user's foot. A nonlimiting example placement for the sensors **32**, **34** is between the foot plate **46** and the sole **49**. As nonlimiting examples, the sensors **32**, **34** may be force-sensitive resistors. The example angle (e.g., rotary) sensor, in the example embodiment shown in FIGS. **2-4**, is supported by the actuator **26**, though this is not necessary in all embodiments. In the example device **20**, the angle sensor is provided by a potentiometer **106** (e.g., 53 Series; Honeywell, Golden Valley) coupled to a shaft **108** on the actuator **26** by a belt **110** for sensing a change in angle between the foot bed **24** and the lower leg mount **22**. Those in the art will appreciate that alternative ways of sensing the angle between the foot bed **24** and the lower leg mount **22** are possible.

FIG. **6** shows interaction among components of the device **20** during an example operation. The rear sensor **34** and fore foot sensor **32** sense pressure on the heel and front foot (e.g., near the toe) of the user during gait, and the angle sensor **36** senses the angle between the lower leg mount **22** and the foot bed **24**. The force sensor readings **32**, **34**, and in example embodiments the angle sensor **36** readings as well, are sent to the on-board controller **30** via the input **90** and more particularly to the microcontroller **96**, which processes the sensor inputs.

The controller **30** then outputs (e.g., via input/output connection **90**) control signals for selectively operating the solenoid valves. The valves are supplied with fluid pressure by the coupling with the fluid power source. One of the valves **72**, selectively controlled by the controller **30**, outputs pressure directly to the pneumatically powered rotary actuator **26** via the input **70**. The other valve **80**, also selectively controlled by the controller, outputs fluid to the second pressure regulator **63**, which in turn provides pressure to the other input **78** of the actuator **26**. The pneumatic power provided by the selectively controlled valves **80**, **82** provides controlled torque and/or resistance for the pneumatically powered actuator **26** to aid or inhibit relative rotation of the lower leg mount **22** and the foot bed **24**.

Generally, to control the device in a first example method, the controller **30** determines the occurrence of particular phases or events within the user's gait cycle, such as by using the readings of the heel sensor **34** and fore foot sensor **32**, and accordingly provides assistance or resistance by switching control of the valves to change direction of torque between dorsiflexor and plantarflexor, provide an appropriate amount of dorsiflexor and/or plantarflexor torque, or allow free range of motion (or substantially free range of motion with mild resistance). An example control scheme is illustrated in FIGS. **7-11**. Other control schemes may be suitable for different users and for different conditions that merit use of the orthosis.

FIG. **7** illustrates control states addressed by the example controller **30** and the actuator **26** during normal gait. Generally, to assist different functional aspects of gait, inputs from the sensors **32**, **34** are processed to provide event boundaries that divide the gait cycle into states during which a particular control action is applied. Four states are determined in an example control method: initial contact or loading response, mid-stance, terminal stance/pre-swing, and swing. These example states are defined as occurring between ("between" can be inclusive or exclusive) four events: heel strike, foot flat, heel off, and toe off. Events can be detected, for example, when sensor magnitudes exceed or drop below tuned user-specific thresholds for the sensors **32**, **34**.

Initial contact (loading response) is defined from heel strike until the foot is flat on the ground. During this state the orthosis **20** provides dorsiflexor assistance to control the velocity of the foot as it travels from heel strike to foot flat, increasing joint impedance to avoid foot slap. Mid-stance lasts from foot flat until the heel comes off the ground, and during this state the orthosis **20** allows (for example) free range of motion at the ankle joint. Terminal stance begins when the heel has come off the ground, and ends when the foot is no longer in contact with the floor, after toe off. Plantarflexor torque (preferably modest torque) is applied during this state to provide assistance at the end of stance for propulsion, as well as stability. Swing, or limb advancement, begins at toe-off and lasts until the heel again makes contact with the ground. Dorsiflexor torque is applied by the orthosis **20** to support the foot in the neutral (or 90 deg) position to maintain clearance during swing and prevent foot drop. Preferably, the sensors **32**, **34**, **36** and programming in the controller can also detect an altered gait, for instance, corresponding to stair climbing or running, by providing suitable feedback.

In example embodiments, the timing of the four states described above and the magnitude of the torque assistance provided can be determined uniquely for each individual and for each condition to be addressed. This can be accomplished in example embodiments using feedback from sensors of the device, e.g., the rear (e.g., heel) sensor **34**, the fore foot sensor **32**, and in some example embodiments the angle sensor **36**, as well as (for instance) measurements from lab equipment, observation from the investigators, and feedback from the participant. Once these values have been determined, a subject specific control scheme can be created and installed, e.g., downloaded, to the microcontroller and memory in the on-board controller **30**.

FIG. **8** illustrates and outlines an example control state of the orthosis **20** during weight acceptance and limb support (the initial contact and mid-stance stages) and provides preferred basic control functions accomplished with the orthosis. The initial contact and mid-stance stages can be defined using event boundaries that occur between heel-strike and heel-off. Thus, the initial contact stage can be defined beginning when the rear sensor **34** reading is above a threshold and ending when both the heel sensor and the fore foot sensor **32** readings are above a threshold (i.e., foot flat). Mid-stance can be defined beginning at foot flat and ending when the rear sensor **34** reading is below the threshold but the fore foot sensor **32** reading is above a threshold (i.e., heel off). The threshold for each event and/or stage in the gait cycle can be set for individual users, devices, etc. During weight acceptance and limb support, there is a functional need for controlled deceleration of the foot (e.g., during initial contact), stability and support during stance, and a free range of motion at the joint (e.g., during mid-stance). This can be accomplished in example embodiments using the device to produce a modest dorsiflexor resist to control the motion of the foot to foot flat.

FIG. **9** illustrates and outlines an example control state of the orthosis **20** during the push off stage. This stage, which extends from heel-off to toe-off, can be defined as beginning at a time when the fore foot sensor **32** reading is above a threshold but the rear sensor **34** reading is not (heel-off), and ending when neither the fore foot sensor reading nor the rear sensor reading is above a threshold (toe-off). At this stage, there is a need for plantarflexor torque assist for propulsion and acceleration of the leg into swing. This can be accomplished by plantarflexor torque assist.

FIG. **10** illustrates and outlines an example control state of the orthosis **20** during swing. Swing extends from a time beginning at toe-off and ending with heel-strike. Thus, the beginning of swing can be determined to occur when both the fore foot **32** and the rear sensor **34** readings are below a threshold. During swing, there is a functional need for dorsiflexor torque to provide toe clearance. This can be accomplished using dorsiflexor torque assist, which in example embodiments can be tuned for the individual user.

FIG. **11** shows an example look-up table and control method for determining the type of torque assist needed during various gait events, using the example event boundaries of heel strike, foot flat, heel off, and toe off. FIG. **11** also shows an example control scheme using this look-up table. In this example control scheme, which can be binary (i.e., dorsiflexor torque assistance or plantarflexor torque assistance is provided entirely or not provided) but need not be in all embodiments, the heel sensor **34** and the front sensor **32** readings are compared to predetermined thresholds, and the results are fed to the look-up table (e.g., "on" indicates a reading above threshold, and "off" indicates a reading below threshold). The controller **30** accordingly can determine the event that has triggered, and it controls the valves **60** in combination with the pressure regulators **62**, **63** and fluid power source **28** to provide plantarflexor torque assistance, dorsiflexor torque assistance, or neither (e.g., during mid-stance). Note that determining the stage of gait can be accomplished by the controller **30** selecting the appropriate control or control scheme for the stage of gait based on the sensor **32**, **34** reading, as shown in FIG. **11**. Also, in the example algorithm shown in FIG. **11**, the angle sensor **36** reading need not be used to determine a particular gait event. In other possible algorithms, the angle sensor **36** reading can be used.

A tuning scheme preferably is provided to determining the timing and magnitude of the device **20** assistance for each user. For example, pressure sensor thresholds can be adjusted for each user to determine event boundaries during the gait cycle. Adjusting sensor thresholds modifies the event boundaries that are determined. In example embodiments, redundant triggers are avoided by maintaining a threshold large enough to exceed the noise level of the unloaded sensors **32**, **34**. Robustness of the determined thresholds may vary, as a nonlimiting example, based on the user or the intended manner of use of the device **20**. Once the sensor thresholds are determined, these can be downloaded to the controller **30**.

FIG. **12** illustrates the first step of a heuristic tuning strategy for the example orthosis **20**, which in the example shown tunes dorsiflexor assist. A user's foot is inserted into the foot bed and is in a relaxed position. This relaxed position moves the foot bed to a position at an obtuse angle with respect to the lower leg mount. To tune the dorsiflexor assist for an individual user in an example embodiment, the pressure regulation is adjusted until the foot moves to a neutral position, at about 90° with respect to the lower leg mount. In some example embodiments, during tuning a ratio and/or coefficient relating pressure and torque is established to control the actuator. The relationship may be linear or substantially linear over the operating range of the actuator, or may be a nonlinear relationship.

FIG. **13** illustrates a second step of a heuristic tuning strategy for the example orthosis **20**, which tunes the timing for determining gait events and stages. The tuning may take place, as nonlimiting examples, in a lab or clinic. The orthosis **20** is fitted to a user, and the user walks wearing the device. Feedback from the heel sensor **34**, front (e.g., toe) sensor **32**, and angle sensor **36** is recorded and analyzed. For example, prior to the beginning of the initial contact stage, the heel sensor readings are analyzed to determine the change in the heel sensor reading between a point when the user's heel is above the ground, and when the heel contacts the ground. For the beginning of the push-off stage, readings for both the heel sensor and the toe sensor are analyzed to determine the change in the heel sensor reading to heel-off and the change in the toe sensor reading as the toe is used for the beginning of push-off. The change in the toe sensor reading after push-off is analyzed to determine the change until toe-off and the beginning of the swing stage.

In some example devices and methods, dorsiflexor and plantarflexor torque are controlled in a binary manner; i.e., either the torque is provided or not. In other example embodiments, dorsiflexor and/or plantarflexor torque can be provided in various intermediate levels. Providing intermediate levels of assistance or resistance allows, among other things, more precise torque assistance, robustness to changing walking conditions, and improved power efficiency and duration.

In an example device according to another embodiment of the invention, the solenoid valves **60** are replaced with one or more high speed proportional solenoid valves (not shown) (one nonlimiting example is LS-V05s; Enfield Technologies, Trumbull, Conn., USA) to allow varying torque assistance. Further, to provide additional robustness and improve pneumatic power efficiency, feedback control, in the form of proportional-integral-derivative (PID) controllers, can be provided.

As shown in the example control system of FIG. **14**, simple PID controllers can be used to accomplish various functional tasks for assisting gait. The force sensor, and in some embodiments also the angle sensor, readings are used to determine an event trigger, which in turn determines which of various tasks are to be performed and thus to open the corresponding valve configuration. The force sensor and angle sensor readings are also converted to an ankle joint angular position, angular velocity, and/or torque, which are compared to an appropriate reference. The result is input to an appropriate PID controller. The PID controller outputs a control torque, which is implemented by the rotary actuator to accomplish the selected task. Example PID controllers have the form,

$$C = k_p + k_i \frac{1}{s} + k_d s,$$

where k_p is the proportional gain, k_i is the integral gain and k_d is the derivative gain. These gains can be determined through heuristic tuning for each of the functional tasks. For example, task 1 can be to track a target velocity reference to control the motion of the foot during loading response, task 2 can be to track a reference force profile during stance for propulsion and stability, and task 3 can be to track an ankle angle reference during swing to control the motion of the foot. In the example shown in FIG. **14**, task 2 is selected.

Example devices provide untethered active ankle foot orthoses that are light weight and small size. A preferred embodiment ankle foot orthosis controls and assists ankle motion using plantarflexor and dorsiflexor torque at the ankle joint, employing pneumatically-powered actuators to provide active ankle torque assistance during gait. Pneumatic power provides high force/weight and force/volume for example actuators, the ability to actuate a joint without a transmission, and the ability to transport pressurized fluid to the actuator through (for example) flexible hoses that can be placed where a shaft from a traditional motor would not reach, among other benefits.

The embedded controller **30** controls the actuation of the foot, and example devices provide the flexibility to modulate the direction (dorsal or plantar), timing, and magnitude of the assistance provided to the user. Advantageously, example devices are flexible enough to accommodate both plantar and dorsiflexor weakness and provide an excellent assistive technology for the compensation of muscle weakness.

Those of ordinary skill in the art will appreciate that various modifications, modifications, substitutions, and alternatives are possible. For example, instead of the pneumatic actuator **26** shown, an orthosis device according to another embodiment of the invention can include a more compact rotary actuator having integrated conduits and valves, for reducing the overall size of the device and/or increasing device efficiency. Additionally, the controller can be an integrated controller, with a suitable power supply and input/outputs. This controller is preferably sufficiently small as to be disposed with the rotary actuator on a portion of a support structure such as a strut to provide a modular subassembly. The controller in such embodiments can be configured to operate according to any of the example methods described herein, or according to other methods. An electronic connection between an integrated controller and the fluid power valves can be provided in particular embodiments. Additionally, an integrated sensor such as a non-contact rotary encoder (e.g., mounted to the actuator) could be provided in place of the belt potentiometer in the device **20**. In addition to control electronics, example controllers can include, as nonlimiting examples, signal processing electronics, data logging capabilities, wireless communication for remote program changes and monitoring, etc.

For example, FIGS. **15**-**23** show a pneumatically powered orthosis device **200** according to another embodiment of the invention. Similar to the orthosis device **20** described above, the orthosis device **200** provides an untethered, powered ankle-foot-orthosis (AFO) design that controls and assists ankle motion using plantarflexor and dorsiflexor torque at the ankle joint. This example device includes a pneumatic rotary actuator **202** to provide active ankle torque assistance during gait. The example orthosis device **200** is self-contained, and preferably uses a portable pneumatic power source (not shown) such as but not limited to the fluid power source **28** used for the device **20**. Alternatively, the orthosis device **200** can include a miniature homogeneous charge compression ignition (HCCI) air compressor power supply, passive noise control, and/or human/machine interfacing.

The orthosis device **200** includes a lower leg or tibial mount component or assembly (lower leg mount) **204** pivotally coupled (e.g., attached) via the rotary actuator **202** to a foot bed component or assembly (foot bed) **206** for relative rotating motion. As with the device **20**, the rotary actuator **202** is disposed at or proximate to an ankle position of a user, e.g., at or near the user's ankle joint. To reduce size and weight of the orthosis device **200**, the free motion ankle joint in the device **20** laterally opposing the rotary actuator **202** is preferably omitted, though in other embodiments, a free motion ankle joint can be provided. The rotary actuator is controlled via an on-board controller, e.g., a microcontroller **208**, disposed on and integrated with the lower leg mount **204**.

As with the lower leg mount **22**, the lower leg mount **204** includes a cuff **210**, or all or part of a sleeve, for accommodating and at least partially supporting a lower leg of the user. The frame of the cuff **210** preferably is as lightweight as possible, while providing sufficient support for the lower leg, and in an example embodiment is composed of a carbon-fiber composite shell, though various other materials can be used (e.g., light metal or plastic). The shell can be integrated with noise and vibration abatement. A strap or straps **212**, e.g., VELCRO® straps or other suitable straps, can be provided for holding the lower leg mount **204** around the user's lower leg. A front plate **213**, as shown in FIG. **17**, can also be provided for supporting the front of the user's lower leg, though this is not required in all embodiments. Suitable padding may be provided between the cuff **210** frame and the user's leg.

The foot bed **206** can be configured for a right or left foot and includes a frame **214** of a sturdy, lightweight material such as carbon-fiber composite, light metal, or plastic. Padding **216** can be provided to line the foot bed **206**. One or more straps **218**, e.g. VELCRO® straps or other suitable straps, preferably are provided for holding the user's foot within the foot bed **206**. A sole **220** (FIGS. **16-17**), which can be similar to the sole **49**, disposed underneath the foot bed **206** provides cushioning for walking. As with the orthosis device **20**, it is contemplated that the foot bed **206** can be configured to fit inside a running or walking shoe, e.g., with the sole **220** being provided by the sole of the shoe.

To reduce overall size and weight of the orthosis device **200**, both the actuator **202** and the controller **208** are integrated into a subassembly **230** incorporated in a support structure for the orthosis device **200**. The example subassembly **230** includes a support structure embodied in a superior-lateral support strut (strut) **232** composed of a rigid and preferably lightweight material (e.g., a light metal). This strut **232** is preferably pivotally coupled to a rigid upper member such as extension **233**, best viewed in FIG. **19**, which is mounted to the foot bed **206**. The strut **232** in the example device **200** is fixedly coupled to the outer (lateral) side of the lower leg mount **204**, e.g., mounted to the shell of the cuff **210**. The actuator **202** and the controller **208** are preferably both disposed on a surface (e.g., a front surface) of the strut **232**.

The actuator **202** includes a back plate **234** (best viewed in FIG. **19**) that preferably is provided by a portion of the front surface of the strut **232**. In the description of the orthosis device **200** with respect to FIGS. **15-23**, "front" is oriented in the direction out of the drawing in FIG. **17**, and "back" is oriented in the direction into the drawing in FIG. **17**. Alternatively, the back plate **234** can be provided by a separate, thin plate suitably mounted to the strut **232** at a similar location, though this will increase the overall thickness of the actuator **202**. Providing the pancake actuator **202**, and providing either a thin back plate **234** or (preferably) incorporating the back plate into the strut **232**, significantly increases compactness of the overall orthosis device **200**. As a nonlimiting example, the complete subassembly **230** can have an overall thickness and weight that is less than the thickness of a commercial rotary actuator such as the rotary actuator **26** in the orthosis device **20**.

As best seen in FIGS. **21-23**, an example rotary actuator **202** is a triple vane pneumatic rotary actuator embodied in a pancake actuator (that is, it has a front-to-back thickness significantly smaller than its diameter). The rotary actuator **202** includes an outer housing (housing) **240** and a rotatable member, e.g., a rotatable triple vane **241** (best viewed in FIG. **23**) disposed within the housing. "Rotatable" as used herein refers to being at least partially rotatable. The housing **240** and the triple vane **242** preferably are made of lightweight, sturdy material, such as but not limited to acrylic. Both the housing **240** and the triple vane **241** may be made of the same material (including composite materials) or of separate materials, and may each be formed as a unitary piece, or as separate components that are assembled.

To provide relative rotation between the lower leg mount **204** and the foot bed **206** the triple vane **241** includes a rotatable central shaft **242**, which is fixedly coupled to the foot bed, for instance mounted to a portion of extension **233**. The triple vane **241** further includes three disposed vanes **243**, **244**, **245**, each of which divide openings in the housing **240** to define first chambers **246***a*, **248***a*, **250***a* and second chambers **246***b*, **248***c*, **250***c* on respective opposing sides of the vanes.

An upper portion **252** of the housing **240** is preferably formed with the housing to be unitary with the housing, but alternatively it may be a separate component that is mounted to the housing. Generally, the upper portion **252** includes integrated conduits and valves for selectively transporting fluid to the first chambers **246***a*, **248***a*, **250***a* and the second chambers **246***b*, **248***c*, **250***c*. For example, the upper portion **252** includes a front inlet port and a rear inlet port **256***a*, **256***b* (in FIG. **21**, the rear inlet port is most clearly viewable), which are in fluid communication with front and rear fluid inputs **257***a*, **257***b* coupled to the inlet ports and disposed on and at least partially within the upper portion **252** of the actuator housing **240**. Additional flow and noise control can be provided with metering valves with silencers, **255***a*, **255***b*, which are provided in an example embodiment (e.g., ASN2; SMC; Japan). The solenoid valves (**260***a*, **260***b*) along with the additional flow control valves (**255***a*, **255***b*) can be configured to manage force produced by the actuator **202**. For instance, the valves (**260***a* and **255***a*) can be used primarily to modulate plantarflexor torque, and the opposite pair of valves (**260***b* and **255***b*) can be used primarily to modulate dorsiflexor torque.

Front and rear valves, e.g., solenoid valves **260***a*, **260***b* are provided for controlling operation of the actuator **202**. The solenoid valves **260***a*, **260***b*, as best viewed in FIG. **20**, are preferably integrated with the upper portion **252** of the actuator housing **204** so that the upper portion provides a housing for the solenoid valves. In this way, both the solenoid valves **260***a*, **260***b* and the fluid regulators **255***a*, **255***b* are integrated with the actuator **202**, reducing overall weight and increasing compactness of the device **200**. The solenoid valves can be, for instance S070B-5DC; SMC; Japan. Instead of solenoid valves, proportional valves (preferably also integrated with the actuator housing **240**) may be used.

The fluid power source (not shown in FIGS. **15-23**), for instance a CO_2 or other suitable fluid container such as bottle **28**, or by a homogeneous charge compression ignition (HCCI) compressor coupled to and disposed on a portion of the leg mount **204**, can be coupled to and in fluid communication with the solenoid valves **260***a*, **260***b*, such as by coupling with fluid lines such as fluid lines **64**, **65**, **66** in the device **20**. Directly integrating the solenoid valves **260***a*, **260***b* with the actuator **202** also reduces the number of additional fluid lines needed. Leads **262** electrically couple the solenoid valves **260***a*, **260***b* to an inlet/outlet **264** of the controller **208** for providing control signals. Fluid outputs of the solenoid valves **260***a*, **260***b* are in fluid communication with the fluid regulators **255***a*, **255***b* respectively, and in turn are in fluid communication with the front and rear inlet ports **256***a*, **256***b*, respectively. Thus, the front solenoid valve **260***a* controls fluid flow to the front inlet port **254***a* and the rear solenoid valve **260***b* controls fluid flow to the rear inlet port **254***b*.

For supplying fluid power to the actuator **202**, the actuator housing **240** includes a front channel **264***a* and a rear channel **264***b* disposed in the housing. The front channel **264***a* fluidly couples the front inlet port **254***a* to the first chambers **246***a*, **248***a*, **250***a*. Similarly, the rear channel **264***b* fluidly couples the rear inlet port **254***b* to the second chambers **246***b*, **248***b*, **250***b*. The use of the valves (solenoid or proportional) enables the selective introduction of pressurized fluid to the actuator **202**. The valving is used to control the torque supplied by the actuator by varying the relative fluid pressure between the first chambers **246***a*, **248***a*, **250***a* and the second chambers **246***b*, **248***b*, **250***b*. The differential pressure across the vane blades **243**, **244**, **245**, generates torque at the shaft used to provide assistance with the device. Seals around the edges of the vane reduce leakage, but still allow vane movement. Operation of the valves **260***a*, **260***b* via the controller **208** can be performed as described above with respect to the device **20**. The first chambers **246***a*, **248***a*, **250***a* and the second chambers **246***b*, **248***b*, **250***b* are also coupled to exit channels that are in turn coupled to the front and rear outlet ports **254***a*, **254***b*, respectively.

The shaft **242** is disposed in a bearing **270** for controlled rotation. Further, the housing **240** includes stops **271**, **272**, **273** symmetrically disposed within the housing to restrict clockwise and counterclockwise rotation of the triple vane **241** beyond a predetermined range. These stops **271**, **272**, **273** also at least partially define outer boundaries of the first and second chambers **246***a*, **248***a*, **250***a*, **246***b*, **248***b*, **250***b*.

Additionally, the face of the actuator body **240** is used to directly seal with the structural subassembly **230**. The body of the actuator **240** can be fastened to the structural subassembly **230** via suitable fasteners **278**. A seal, for example a silicone seal, may be disposed between the actuator body **240** and the structural subassembly **230**.

The front cover **276** preferably further includes an outer front plate **280** (see FIG. **20**) for accommodating an angle sensor **282** (see FIGS. **17-18**). Preferably, the angle sensor **282** has no moving parts. A preferred angle sensor **282** is a thin, non-contact rotary encoder, e.g., QR30; Dewitt Industrial Sensors; Netherlands, which is mounted to the outer front plate **280** via suitable fasteners **284**. Leads **286** or other signal couplings (wired or wireless) are provided for providing signals from the angle sensor **282** for the controller **208**. In other example embodiments, the angle sensor **282** (and leads **286**) can be omitted.

Thus, in the example orthosis device **200**, the solenoid valves **260***a*, **260***b*, metering valves with silencers, **255***a*, **255***b*, with suitable conduits, fluid outputs **257***a*, **257***b*, and the angle sensor **282** are integrated directly into the actuator housing **240**. The electrical connections between the controller **208** and the solenoid valves **260***a*, **260***b* can also be disposed at least partially on or in the actuator housing **240**. Further, the actuator **202** preferably is integrated directly into the structural sub-assembly **230**, such as by incorporating a portion of the strut **232** for a back plate or by otherwise mounting a thin back plate to the strut. Thus, the example orthosis device **200** can weigh less and be smaller than other comparable devices, while also exhibiting increased efficiency.

The controller **208** is provided in an example embodiment on a circuit board **300** (e.g., a printed circuit board (PCB)) that is made sufficiently small as to be disposed on (and preferably fit entirely within) the surface of the strut plate **232**. This circuit board **300** preferably is generally enclosed in a casing that is provided by a rear plate **302** (best viewed in FIG. **18**) and a front cover **304**, which may be vented. A battery **306** or other suitable power source (such as, but not limited to, the example power source **98**) coupled to the circuit board **300** via suitable leads **308** supplies power to the controller **208** as will be appreciated by one of ordinary skill in the art. An on/off switch **310** is preferably provided on the circuit board **300**.

Circuit components for the controller **208**, including a microprocessor **316**, and suitable electrical components **312**, **314**, **318** as well as the switch **310** and the input/output port **264**, are integrated on the circuit board **300** as will be appreciated by one of ordinary skill in the art. Other components, for instance, for data logging capabilities, wireless communication for remote program changes and monitoring, etc., can also be provided. It will also be understood that the particular selection and arrangement of the circuit components for the controller **208** can vary, and the present invention is not intended to be limited to the particular controller shown.

The input/output port **264** mounted on the circuit board **300** provides output control signals to the integrated solenoid valves **260***a*, **260***b* via the leads **262**. The input/output port **264** also receives input signals from the angle sensor **282** via leads **286**. Further, leads **330** are provided for electrically coupling the input/output port **264** to force sensors such as the sensors **32**, **34**, **36** in the orthosis device **20**. It is also contemplated that the signal leads **262**, **330** could be omitted if the signals are transmitted wirelessly. It will further be appreciated that the input/output port **264** could include separate or integrated input and output ports.

As with the device **20**, timing and magnitude for the orthosis device **200** can be determined uniquely for each participant through electronic and mechanical methods and devices/systems. For example, this can be accomplished using feedback from sensors, measurements from lab equipment, observation from investigators, and/or feedback from the participant to determine a subject specific control scheme that is downloaded to the microprocessor **312** embedded on the circuit board **300**.

By providing a compact electronics package for the controller **208**, the controller, the actuator **202**, the solenoid valves **260***a*, **260***b*, the fluid regulators **255***a*, **255***b*, and the angle sensor **282**, with suitable fluid conduits and signal couplings, can be integrated onto the strut **232** to provide the single, integrated subassembly **230**. This complete subassembly **230** according to embodiments of the present invention can provide all aspects of the device's **200** functionality (e.g., other than the force sensing taking place underneath the user's foot) when provided with power for the controller **208** and fluid power for the actuator **202**, yet this subassembly is lighter (as a nonlimiting example, 18 grams less) and thinner (as a nonlimiting example, 17% narrower) than some commercial rotary actuators. The subassembly **230**, supported by the strut **232**, also provides a modular solution for the active orthosis device **200**, and could be integrated into other overall orthosis devices to provide controlled, active assistance. Operation of the orthosis device **200** is also made more efficient, and thus can be made more powerful, by integrating the components as shown and described in example embodiments. A nonlimiting example embodiment rotary actuator **202** produces 6.2 Nm of output torque given an input of 50 psi pneumatic pressure.

Example devices of the invention are lightweight and are configured, dimensioned, and arranged to be useable with many types of normal footwear and clothing. The lightweight design and compact, close-fitting nature of example devices also minimize the energetic impact to a user. Orthoses according to example embodiments of the invention are well-suited for at-home therapy and also for daily wear usage, because the devices are untethered and preferably lightweight. Example orthoses provide a treatment modality to improve the functional outcome of rehabilitation, diagnostic or training services, and/or laboratory studies.

While various embodiments of the present invention have been shown and described, it should be understood that other modifications, substitutions, and alternatives are apparent to one of ordinary skill in the art. Such modifications, substitutions, and alternatives can be made without departing from the spirit and scope of the invention, which should be determined from the appended claims.

Various features of the invention are set forth in the appended claims.

What is claimed is:

1. A portable active pneumatically powered ankle foot orthosis comprising:

a lower leg mount;

a foot bed pivotally configured to be coupled to said lower leg mount at or proximate to an ankle position;

at least one sensor for determining a phase of a user's gait;

a pneumatically powered rotary actuator coupled to said leg mount and to said foot bed, said rotary actuator being configured to receive power from a wearable fluid power source and to provide controlled force and/or resistance to aid or inhibit relative rotation of said foot bed and said lower leg mount; and

a controller for receiving data from said at least one sensor and controlling said pneumatically powered rotary actuator to actively assist gait of a user wherein said pneumatically powered rotary actuator comprises a pancake actuator having a front-to-back thickness significantly smaller than its diameter;

wherein said rotatable member comprises a shaft coupled to at least one vane;

wherein said pneumatically powered rotary actuator comprises a plurality of openings disposed within said outer housing such that each of the least one vane is disposed within one of the plurality of openings to divide each of the plurality of openings into first and second fluid chambers;

wherein said pneumatically powered rotary actuator further comprises:

first and second fluid inputs integrated with said outer housing; and

first and second fluid channels, wherein said first fluid channel fluidly couples said first fluid input with each of the first fluid chambers, and said second fluid channel fluidly couples said second input with each of the second fluid chambers.

2. The device of claim 1, further comprising:

at least one actuated valve for connecting to said wearable fluid power source and controlling fluid flow to said pneumatically powered rotary actuator;

said at least one actuated valve being responsive to said controller.

3. The device of claim 2, wherein said wearable fluid power source comprises a compact, wearable fluid power source coupled to said at least one valve and said pneumatically powered rotary actuator.

4. The device of claim 3, wherein said wearable fluid power source comprises a container housing a compressible fluid.

5. The device of claim 2, further comprising:

a pressure regulator coupled to said at least one actuated valve and to said pneumatically powered rotary actuator.

6. The device of claim 1, wherein said lower leg mount and said foot bed comprise a rigid, lightweight material selected from the group consisting of carbon fiber, carbon composite, light metal, and plastic.

7. The device of claim 1, wherein said controller is integrated with at least one of said lower leg mount and said foot bed;

wherein said controller comprises a microprocessor and a memory.

8. The device of claim 1, further comprising:

an angle rotation sensor for sensing an angle between said lower leg mount and said foot bed.

9. The device of claim 1, wherein said at least one sensor comprises at least one force sensor coupled to said foot bed for receiving a force applied to at least one portion of the foot bed and generating a signal.

10. A portable active pneumatically powered ankle foot orthosis comprising:

a lower leg mount;

a foot bed pivotally configured to be coupled to said lower leg mount at or proximate to an ankle position;

at least one sensor for determining a phase of a user's gait;

a pneumatically powered rotary actuator coupled to said lower leg mount and to said foot bed, said pneumatically powered rotary actuator being configured to receive power from a wearable fluid power source and to provide controlled force and/or resistance to aid or inhibit relative rotation of said foot bed and said lower leg mount, wherein said pneumatically powered rotary actuator comprises an outer housing, a rotatable member disposed within said outer housing, and at least one valve integrated with said pneumatically powered rotary actuator; and

a controller for receiving data from said at least one sensor and controlling said pneumatically powered rotary actuator by controlling said at least one valve to actively assist the user's gait, wherein said pneumatically powered rotary actuator comprises a pancake actuator having a front-to-back thickness significantly smaller than its diameter;

wherein said rotatable member comprises a shaft coupled to at least one vane;

wherein said pneumatically powered rotary actuator comprises a plurality of openings disposed within said outer housing such that each of the least one vane is disposed within one of the plurality of openings to divide each of the plurality of openings into first and second fluid chambers;

wherein said pneumatically powered rotary actuator further comprises:

first and second fluid inputs integrated with said outer housing; and

first and second fluid channels, wherein said first fluid channel fluidly couples said first fluid input with each of the first fluid chambers, and said second fluid channel fluidly couples said second input with each of the second fluid chambers.

11. The ankle foot orthosis of claim 10, wherein said at least one valve comprises at least one of a solenoid valve and a proportional valve.

12. The ankle foot orthosis of claim 10, further comprising:

a silencer disposed at least partially within said outer housing.

13. The ankle foot orthosis of claim 10, further comprising:

a front cover attached to and at least partially covering said outer housing.

14. The ankle foot orthosis of claim 13, further comprising:

an angle sensor integrated with said pneumatically powered rotary actuator;

wherein said angle sensor comprises a rotary encoder coupled to said front cover.

15. The ankle foot orthosis of claim 10, wherein said rotary actuator and said controller are fixedly coupled to a surface of a support structure to provide a subassembly;

wherein the subassembly is coupled to said lower leg mount;

wherein said rotary actuator, said controller, and said at least one valve are integrated on the subassembly.

16. The ankle foot orthosis of claim **15**, wherein said controller comprises:

a circuit board disposed on a surface of the strut;

a processor disposed on said circuit board; and

at least one of an input port and an output port disposed on said circuit board;

wherein said circuit board is sized to fit within the surface of the strut.

17. The ankle foot orthosis of claim **10**, further comprising a strut coupling said lower leg mount to said pneumatically powered rotary actuator.

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